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Legislation and Regulation Committee

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LEGISLATION AND REGULATION COMMITTEE REPORT AND ACTION

Report of the Legislation and Regulation Committee Meeting of January 7, 2009

B. LEGISLATIVE REPORT AND ACTION

1. Legislation Sponsored by the Board of Pharmacy

   a. **Information Only** - Reintroduction of 2008 Omnibus Provisions Contained in SB 1779 (2008)

Attachment B-1

At the October 2008 Board Meeting, the board voted to pursue all of the omnibus provisions approved for sponsorship in 2008. Many of these provisions were included in SB 1779 (Senate Business and Professions Committee) which was vetoed by the Governor.

These omnibus provisions were categorized into four types of changes:

1. Use of mobile pharmacies.
2. Changes resulting in a comprehensive legal review by board staff and counsel on the legal requirements surrounding the Pharmacist-in-Charge and Designated Representative-in-Charge.
3. General omnibus provisions.
4. Omnibus provisions resulting from the recodification of Business and Professions Code section 4052.

Below is a summary of the changes by category and section.

Use of Mobile Pharmacies

Section 4062 Furnishing Dangerous Drugs During an Emergency
This section allows for the use of a mobile pharmacy in the event of a declared natural disaster if certain criteria are met.

Section 4110 License Required, Temporary Permit Upon Transfer of Ownership
This section allows for the use of a mobile pharmacy on a temporary basis when a pharmacy is destroyed or damaged.

Pharmacist-in-Charge and Designated Representative-in-Charge

Consistent with the board's strategic objective 3.3, board staff and counsel completed a comprehensive review of the legal requirements surrounding the requirements of a pharmacist-in-charge (PIC) as well as a designated representative-in-charge (DRIC). As a result of this review, several omnibus changes were recommended to include some technical changes as well as refine the definitions of the pharmacist-in-charge and designated representative-in-charge and clarify the reporting requirements when a change of PIC or DRIC occurs. These changes were approved by the board and many were incorporated in SB 1779 as omnibus provisions. This bill was vetoed by the Governor. Board staff recommends that the board again consider including these changes as omnibus provisions in 2009.

Below is a list of the specific recommended changes as well as a brief statement about the specific proposed changes. The proposed language is following this memo.

Section 4022.5 – Designated Representative; Designated Representative-in-Charge
This section requires amendment to clarify the definition of "designated representative-in-charge" as well as the responsibilities of a licensee serving as such.

Section 4036.5 – Pharmacist-in-Charge
A new section is needed to define the term "pharmacist-in-charge" as well as the responsibilities a pharmacist serving as such.

Section 4161 – Non-Resident Wholesaler; Requirements
This section requires amendment to further clarify the duties that constitute a business operating as a non-resident wholesaler. This definition is already provided in B&PC § 4043.

Section 4305 – Pharmacist-in-Charge; Notice to Board; Disciplinary Action
This section requires amendment to specify that failure to meet notification requirements will constitute grounds for disciplinary action.

Section 4329 – Nonpharmacists; Prohibited Acts
This section requires amendment to include the prohibition of a nonpharmacist from acting as a supervisor or pharmacist-in-charge.

Section 4330 – Proprietors; Prohibited Acts
This section requires amendment to clarify that any pharmacy owner that subverts or tends to subvert the efforts of a pharmacist-in-charge is guilty of a misdemeanor.

General Omnibus Provisions

In addition to the changes listed above, all of the following proposals were also approved as omnibus provisions for 2008:

Section 4059.5 - Who May order Dangerous Drugs or Devices, Exceptions.
A technical change to this section is necessary to clarify that a designated representative must sign for and receive delivery of drugs by a wholesaler.

Section 4081 – Records of Dangerous Drugs or Devices Kept Open for Inspection ; Maintenance of Records, Current Inventory
This section requires amendment to replace the term "representative-in-charge" with "designated representative-in-charge."

Section 4126.5 – Furnishing Dangerous Drugs by Pharmacy
This section requires amendment to clarify specifically who in the supply chain may receive dangerous drugs furnished by a pharmacy.

Section 4231 – Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee
This section requires amendment to expand the board's authority to also include the board's ability to automatically inactivate a pharmacist license when a pharmacist who certifies completion of the required CE as part of a renewal, fails to provide proof either as part of an audit or investigation initiated by the board.

H&SC 11165 – Controlled Substance Utilization Review and Evaluation System: Establishment; Operation; Funding; Reporting to Legislature
This section requires amendment to require that a clinic that dispensed schedule III and schedule IV controlled substances must report to CURES.

Omnibus Provisions Resulting from Recodification of Business and Professions Code §4052 **Attachment B-2**

In 2006 Business and Professions Code section 4052 was recodified into four sections. As a result, the following B&PC sections and H&SC section reference 4052 and require technical updates.

Section 733 – Dispensing Prescription Drugs and Devices
Section 4027 – Skilled Nursing Facililty – Intermediate Care Facility – Other Health Care Facilities
Section 4040 – Prescription; Content Requirements
Section 4051 – Conduct Limited to Pharmacist; Conduct Authorized by Pharmacist
Section 4060 – Controlled Substance – Prescription Required, Exceptions
Section 4076 – Prescription Container – Requirements for Labeling
Section 4111 – Restrictions on Prescriber Ownership
Section 4174 – Dispensing by Pharmacist Upon Order of Nurse Practitioner
H&SC 11150 – Persons Authorized to Write or Issue a Prescription

Board staff was advised by the Senate Business and Professions Committee that SB 1779 (2008) will be reintroduced as passed by both the assembly and senate. No additional changes will be incorporated into this bill. While board staff does not anticipate any opposition, should it occur, board members will be advised.

b. ***FOR ACTION*** - Omnibus Provisions for 2009

Attachment B-3

The board should determine whether it wishes to reaffirm pursuit of these omnibus provisions in the 2009-2010 Legislative session.

At the October 2008 Board Meeting, the board voted to pursue several new omnibus provisions, as well as previously approved omnibus provisions, that were not incorporated in SB 1779 (2008).

Add Section 4146 – Disposal of Returned Sharps by a Pharmacy
This section needs to be added to allow a pharmacy to accept returned sharps containers from consumers for disposal.

Add Section 4013 – Subscriber Alert
This section needs to be added to require all board licensed facilities to join the board's e-mail notification list.

Amend Section 4112 – Nonresident Pharmacy: Registration; Provision of Information to Board; Maintaining Records; Patient Consultation
This section requires amendment to explicitly state that a person cannot act as a nonresident pharmacy unless he or she has obtained a license from the state.

Section 4101 – Pharmacist-in-Charge; Designated Representative-in-Charge; Termination of Status; Duty to Notify the Board.
This section requires amendment to clarify when a pharmacist-in-charge or designated representative-in-charge must notify the board that he or she ceased to serve in such a capacity.

Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications
This section requires amendment to clarify the procedures to be followed by a pharmacy when identifying a pharmacist-in-charge as well as the procedures to notify the board when a change in pharmacist-in-charge has occurred. In addition, this section allows for the use of an interim pharmacist-in-charge, for a period not greater than 120 days, when a pharmacy is unable to identify a permanent new pharmacist-in-charge within 30 days as required.

Section 4160 – Wholesaler Licenses
This section requires amendment to clarify the procedures to be followed by a wholesaler when identifying a designated representative-in-charge as well as the procedures to notify the board when a change in the designated representative-in-charge has occurred.

Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked
This section requires amendment to clarify the procedures to be followed by a veterinary food-animal drug retailer when identifying a designated representative-in-charge as well as the procedures to notify the board when a change in the designated representative-in-charge has occurred.

Section 4362 – Entry Into Pharmacists Recovery Program
This section requires amendment to specify the administrative co-pay that participants pay.

Section 4200.1 – Retaking Examinations; Set Limits; Requirements
This section requires amendment to repeal the sunset of this provision.
Attachment 2 contains language that was submitted to the Senate Business and Professions Committee for inclusion in the omnibus bill. While we do not anticipate any opposition to these provisions, should any arise, board members will be advised.

c. ***FOR INFORMATION*** – Immunization Proposal – Amendment to Business and Professions Code Section 4052 and Addition of Section 4052.8

Attachment B-4

At the October 2008 Board Meeting, the board voted to pursue a statutory change to allow a pharmacist to initiate and administer immunizations pursuant to the published recommendations of the Advisory Committee on Immunization Practices (ACIP).

Beginning in November 2007, board staff worked with stakeholders to address questions as well as to elicit support for this proposal for sponsorship in 2008. However, in April 2008, after consideration it was decided not to move the proposal last year due to a lack of staff and other legislative priorities.

Board staff is contacting potential authors for this proposal and will resume stakeholder meetings in February 2009 to solidify a broad base of support for this proposal.

Attachment B-4 contains a copy of the proposed language, a copy of the ACIP Adult and Adolescent Immunization Schedules as well as some fact sheets on the topic.

d. ***FOR INFORMATION*** – Elements of a Prescription Label – Amendment to Business and Professions Code Section 4076

Attachment B-5

At the October 2008 Board Meeting, the board voted to pursue a statutory change to replace the "condition" for which a prescription is prescribed, with the "purpose" for which the medicine is prescribed. This change will clarify a pharmacist's authorization within Business and Professions Code section 4076(a)(10) and allow a pharmacist to place the "purpose" of the medication on the label that is affixed to every prescription container dispensed to a patient, if requested by the patient. This proposal is consistent with the results of the board's prescription label survey where approximately 19% of all respondents requested the purpose of the medicine be included on the label.

Board staff is contacting potential authors for this proposal and is working the California Pharmacy Foundation.

Attachment B-5 contains a copy of the proposed language as well as a fact sheet.

2. **Legislative Proposal Regarding Return of Medicine to Reverse Distributors**

FOR ACTION – Amendment to Business and Professions Code sections 4040.5, 4043 and 4081. **Attachment B-6**

Committee Recommendation: To recommend the addition of this proposal to amplify regulatory structure of reverse distributors to the board's legislative calendar for 2009 including amendment to Business and Professions Code sections 4040.5, 4043 and 4081.

Should the board vote to pursue these changes, board staff will contact potential authors for sponsorship.

For several years, the board has been involved in the issue of take-back drugs, where patients can return unwanted medicine (both OTC and prescription) to pharmacies for disposal instead of tossing them in the garbage or flushing them down the toilet.

Currently, the board is working with the California Integrated Waste Management Board along with several other state agencies and the California Department of Public Health on model programs for take back drugs. Model program guidelines were put in place December 1, 2008, as required by SB 966 (Simitian, Chapter 542, Statutes of 2007). The California Integrated Waste Management Board may make several amendments to these guidelines, possibly in February 2009. No amendments to the guidelines are currently available, although they may be by the time of the January 2009 Board Meeting.

In working with these agencies, there appears to be some confusion over when a licensed integrated waste hauler (licensed by the California Department of Public Health) and a licensed reverse distributor (licensed by the Board of Pharmacy) may pick up unsaleable medicine from a licensed or non-licensed facility.

In general, aggregate pharmaceutical waste, as occurs in take back programs whether operated by pharmacies or at community events where medicine is comingled/mixed with multiple drugs, needs to be handled by licensed integrated waste haulers. Specifically, statutes enforced by CDPH require that once home-generated pharmaceutical waste has been consolidated at a facility or place of business, the waste must be managed as medical or hazardous waste. This includes all statutory requirements for storage and handling, and transportation.

Reverse distributors handle those drugs that are unsaleable and are returned by a pharmacy or a practitioner—not those returned by patients.

Pharmacies can return unwanted drugs in a variety of ways, as identified below.

- To the wholesaler from which it purchased the drugs. This provision was created as part of the pedigree provisions to prevent a pharmacy from acting as a wholesaler.
- To a reverse distributor (a licensed wholesaler) if the drugs are unsaleable.
- To an integrated waste hauler (for disposal) and for all drugs taken back by the pharmacy from patients.

Based on discussion during the committee meeting, board staff will survey some drug manufacturers to identify how they currently determine the quantity as specified in B&PC § 4081(b).

3. **Legislation Introduced Impacting the Practice of Pharmacy or the Board's Jurisdiction**

FOR INFORMATION

Although very early in the session, two bills have been introduced impacting the practice of pharmacy or the board's jurisdiction.

a. **AB 67** (Nava) Pharmacy Patient Protection Act of 2008

This bill would establish the Pharmacy Patient Protection Act of 2008, which would require pharmacists to dispense all lawfully obtained prescriptions when the prescribed medication is in stock without regard to any ethical, moral, or religious objections.

Board staff was recently advised by the author that this proposal will not be pursued. According to Nava's office, they have done a lot of research and concluded that consumers are adequately protected under current law.

b. **SB 26** (Simitian) Home Generated Pharmaceutical Waste **Attachment B-7**

This bill would require the board to coordinate with other state agencies, local governments, drug manufacturers, and pharmacies to develop sustainable, efficient policies and programs to manage pharmaceutical wastes and the disposal of devices. The bill would authorize a pharmacy to accept the return of home-generated pharmaceutical waste and home-generated sharps waste, as defined.

4. **Additional California Legislation Introduced Affecting the Board's Regulatory Jurisdiction.**

Board staff continue to monitor introduced legislation and will bring any new proposals to the board meeting.

Attachment B-1

2008 Omnibus Provisions Contained in SB 1779 (2008)

Business and Professions Code Amendments

Use of Mobile Pharmacies

§ 4062. Furnishing Dangerous Drugs During and Emergency

(a) Notwithstanding Section 4059 or any other provision of law, a pharmacist may, in good faith, furnish a dangerous drug or dangerous device in reasonable quantities without a prescription during a federal, state, or local emergency, to further the health and safety of the public. A record containing the date, name, and address of the person to whom the drug or device is furnished, and the name, strength, and quantity of the drug or device furnished shall be maintained. The pharmacist shall communicate this information to the patient's attending physician as soon as possible. Notwithstanding Section 4060 or any other provision of law, a person may possess a dangerous drug or dangerous device furnished without prescription pursuant to this section.

(b) During a declared federal, state, or local emergency, the board may waive application of any provisions of this chapter or the regulations adopted pursuant to it if, in the board's opinion, the waiver will aid in the protection of public health or the provision of patient care.

(c) During a declared federal, state, or local emergency the board will allow for the deployment of a mobile pharmacy to impacted areas to ensure the continuity of patient care if all of the following conditions are met:

(1) The mobile pharmacy shares common ownership with at least one currently licensed pharmacy in good standing;
(2) The mobile pharmacy retains records of dispensing as required in subdivision (a);
(3) A licensed pharmacist is on the premises, and the mobile pharmacy is under the control and management of a pharmacist while the drugs are being dispensed;
(4) Reasonable security measures are taken to safeguard the drug supply maintained in the mobile pharmacy;
(5) The mobile pharmacy is located within the declared disaster area or affected areas; and
(6) The mobile pharmacy ceases the provisions of services within forty-eight (48) hours following the termination of the declared emergency.

§ 4110 License Required, Temporary Permit Upon Transfer of Ownership

(a) No person shall conduct a pharmacy in the State of California unless he or she has obtained a license from the board. A license shall be required for each pharmacy owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a pharmacy in more than one location. The license shall be renewed annually. The board may, by regulation, determine the circumstances under which a license may be transferred.

(b) The board may, at its discretion, issue a temporary permit, when the ownership of a pharmacy is transferred from one person to another, upon the conditions and for any periods of time as the board determines to be in the public interest. A temporary permit fee shall be established by the board at an amount not to exceed the annual fee for renewal of a permit to conduct a pharmacy. When needed to protect public safety, a temporary permit may be issued for a period not to exceed 180 days, and may be issued subject to terms and conditions the board deems necessary. If the board determines a temporary permit was issued by mistake or denies the application for a permanent license or registration, the temporary license or registration shall terminate upon either personal service of the notice of termination upon the permitholder or service by certified mail, return receipt requested, at the permitholder's address of record with the board, whichever comes first. Neither for purposes of retaining a temporary permit nor for purposes of any disciplinary or license denial proceeding before the board shall the temporary permitholder be deemed to have a vested property right or interest in the permit.
(c) The board may allow the temporary use of a mobile pharmacy, when a pharmacy is destroyed or damaged and when needed to protect the health and safety of the public and the following conditions are met:

(1) The mobile pharmacy shall provide services only on or immediately contiguous to the site of the damaged or destroyed pharmacy.
(2) The mobile pharmacy is under the control and management of the Pharmacits-in-Charge of the pharmacy that was destroyed or damaged.
(3) A licensed pharmacist is on the premises while drugs are being dispensed.
(4) Reasonable security measures are taken to safeguard the drug supply maintained in the mobile pharmacy.
(5) The pharmacy operating the mobile pharmacy provides the board with records of the destruction or damage and an expected restoration date.
(6) Within three (3) calendar days of restoration of the pharmacy services, the board is provided with notice of the restoration to the permanent pharmacy.
(7) The mobile pharmacy is not operated for more than forty-eight (48) hours following the restoration of the pharmacy.

Changes resulting in a comprehensive legal review by board staff and counsel on the legal requirements surrounding the Pharmacist-in-Charge and Designated Representative-in-Charge

§ 4022.5. Designated representative; designated representative-in-charge

(a) "Designated representative" means an individual to whom a license has been granted pursuant to Section 4053. A pharmacist fulfilling the duties in Section 4053 shall not be required to obtain a license as a designated representative.

(b) "Designated representative-in-charge" means a designated representative or a pharmacist proposed by a wholesaler or veterinary food-animal drug retailer and approved by the board ~~who is~~ as the supervisor or manager ~~of a~~ responsible for ensuring the wholesaler's or veterinary food-animal drug retailer's compliance with all state and federal laws and regulations pertaining to practice in the applicable license category.

§ 4036.5. Pharmacist-in-charge

"Pharmacist-in-charge" means a pharmacist proposed by a pharmacy and approved by the board as the supervisor or manager responsible for ensuring the pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

§ 4161. Out-of-State Distributor; Requirements

4161. (a) A person located outside this state that *(1)* ships, *sells,* mails, or delivers dangerous drugs or dangerous devices into this state *or (2) sells, brokers, or distributes dangerous drugs or devices within this state* shall be considered a nonresident wholesaler.
(b) A nonresident wholesaler shall be licensed by the board prior to shipping, *selling,* mailing, or delivering dangerous drugs or dangerous devices to a site located in this state *or selling, brokering, or distributing dangerous drugs or devices within this state* .
(c) A separate license shall be required for each place of business owned or operated by a nonresident wholesaler from or through which dangerous drugs or dangerous devices are shipped, *sold,* mailed, or delivered to a site located in this state *or sold, brokered, or distributed within this state* . A license shall be renewed annually and shall not be transferable.
(d) The following information shall be reported, in writing, to the board at the time of initial application for licensure by a nonresident wholesaler, on renewal of a nonresident wholesaler license, or within 30 days of a change in that information:
(1) Its agent for service of process in this state.
(2) Its principal corporate officers, as specified by the board, if any.
(3) Its general partners, as specified by the board, if any.
(4) Its owners if the applicant is not a corporation or partnership.
(e) A report containing the information in subdivision (d) shall be made within 30 days of any change of ownership, office, corporate officer, or partner.
(f) A nonresident wholesaler shall comply with all directions and requests for information from the regulatory or licensing agency of the state in which it is licensed, as well as with all requests for information made by the board.
(g) A nonresident wholesaler shall maintain records of dangerous drugs and dangerous devices sold, traded, or transferred to persons in this state, so that the records are in a readily retrievable form.
(h) A nonresident wholesaler shall at all times maintain a valid, unexpired license, permit, or registration to conduct the business of the wholesaler in compliance with the laws of the state in which it is a resident. An application for a nonresident wholesaler license in this state shall include a license verification from the licensing authority in the applicant's state of residence.
(i) The board may not issue or renew a nonresident wholesaler license until the nonresident wholesaler identifies a designated representative-in-charge and notifies the board in writing of the identity and license number of the designated representative-in-charge.
(j) The designated representative-in-charge shall be responsible for the nonresident wholesaler's compliance with state and federal laws governing wholesalers. A nonresident wholesaler shall identify and notify the board of a new designated representative-in-charge within 30 days of the date that the prior designated representative-in-charge ceases to be the designated representative-in-charge.
(k) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A temporary license fee shall be five hundred fifty dollars ($550) or another amount established by the board not to exceed the annual fee for renewal of a license to compound injectable sterile drug products. When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, subject to terms and conditions that the board deems necessary. If the board determines that a temporary license was issued by mistake or denies the application for a permanent license, the temporary

license shall terminate upon either personal service of the notice of termination upon the licenseholder or service by certified mail, return receipt requested, at the licenseholder's address of record with the board, whichever occurs first. Neither for purposes of retaining a temporary license, nor for purposes of any disciplinary or license denial proceeding before the board, shall the temporary licenseholder be deemed to have a vested property right or interest in the license.
(l) The registration fee shall be the fee specified in subdivision (f) of Section 4400.

§ 4305. ~~Licensees conducting pharmacies;~~ Pharmacist-in-charge; notice to board; disciplinary action

(a) ~~Any person who has obtained a license to conduct a pharmacy, shall notify the board within 30 days of the termination of employment of any pharmacist who takes charge of, or acts as manager of the pharmacy.~~ Failure by any pharmacist to notify the board in writing that he or she has ceased to act as pharmacist-in-charge of a pharmacy, or by any pharmacy to notify the board in writing that a pharmacist-in-charge is no longer acting in that capacity, within the 30-day period specified by sections 4101 and 4113, shall constitute grounds for disciplinary action.

(b) Operation of a pharmacy for more than 30 days without supervision or management thereof by a pharmacist-in-charge shall constitute grounds for disciplinary action.

(~~b~~ c) Any person who has obtained a license to conduct a pharmacy, who willfully fails to timely notify the board ~~of the termination of employment of~~ that ~~any pharmacist who takes charge of, or acts as manager~~ the pharmacist-in-charge of the pharmacy has ceased to act in that capacity, and who continues to permit the compounding or dispensing of prescriptions, or the furnishing of drugs or poisons, in his or her pharmacy, except by a pharmacist subject to the supervision and management of a responsible pharmacist-in-charge, shall be subject to summary suspension or revocation of his or her license to conduct a pharmacy.

~~(c) Any pharmacist who takes charge of, or acts as manager of a pharmacy, who terminates his or her employment at the pharmacy, shall notify the board within 30 days of termination of employment. Failure to notify the board within the 30-day period shall constitute grounds for disciplinary action.~~

§ 4329. Nonpharmacists; prohibited acts

Any nonpharmacist who takes charge of or acts as supervisor, manager, or pharmacist-in-charge of any pharmacy, or who compounds or dispenses a prescription or furnishes dangerous drugs except as otherwise provided in this chapter, is guilty of a misdemeanor.

§ 4330. Proprietors; prohibited acts

(a) Any person who has obtained a license to conduct a pharmacy, who fails to place in charge of the pharmacy a pharmacist, or any person, who by himself or herself, or by any other person, permits the compounding or dispensing of prescriptions, or the furnishing of dangerous drugs, in his or her pharmacy, except by a pharmacist, or as otherwise provided in this chapter, is guilty of a misdemeanor.

(b) Any ~~nonpharmacist~~ pharmacy owner who commits any act that would subvert or tend to subvert the efforts of the pharmacist-in-charge to comply with the laws governing the operation of the pharmacy is guilty of a misdemeanor.

General Omnibus Provisions

§ 4059.5. Who may order dangerous drugs or devices, exceptions

(a) Except as otherwise provided in this chapter, dangerous drugs or dangerous devices may only be ordered by an entity licensed by the board and shall be delivered to the licensed premises and signed for and received by a pharmacist. Where a licensee is permitted to operate through a designated representative, ~~the~~ a designated representative ~~may~~ must sign for and receive the delivery.

(b) A dangerous drug or dangerous device transferred, sold, or delivered to a person within this state shall be transferred, sold, or delivered only to an entity licensed by the board, to a manufacturer, or to an ultimate user or the ultimate user's agent.

(c) Notwithstanding subdivisions (a) and (b), deliveries to a hospital pharmacy may be made to a central receiving location within the hospital. However, the dangerous drugs or dangerous devices shall be delivered to the licensed pharmacy premises within one working day following receipt by the hospital, and the pharmacist on duty at that time shall immediately inventory the dangerous drugs or dangerous devices.

(d) Notwithstanding any other provision of law, a dangerous drug or dangerous device may be ordered by and provided to a manufacturer, physician, dentist, podiatrist, optometrist, veterinarian, naturopathic doctor pursuant to Section 3640.7, or laboratory, or a physical therapist acting within the scope of his or her license. A person or entity receiving delivery of a dangerous drug or dangerous device, or a duly authorized representative of the person or entity, shall sign for the receipt of the dangerous drug or dangerous device.

(e) A dangerous drug or dangerous device shall not be transferred, sold, or delivered to a person outside this state, whether foreign or domestic, unless the transferor, seller, or deliverer does so in compliance with the laws of this state and of the United States and of the state or country to which the dangerous drugs or dangerous devices are to be transferred, sold, or delivered. Compliance with the laws of this state and the United States and of the state or country to which the dangerous drugs or dangerous devices are to be delivered shall include, but not be limited to, determining that the recipient of the dangerous drugs or dangerous devices is authorized by law to receive the dangerous drugs or dangerous devices.

(f) Notwithstanding subdivision (a), a pharmacy may take delivery of dangerous drugs and dangerous devices when the pharmacy is closed and no pharmacist is on duty if all of the following requirements are met:

(1) The drugs are placed in a secure storage facility in the same building as the pharmacy.
(2) Only the pharmacist-in-charge or a pharmacist designated by the pharmacist-in-charge has access to the secure storage facility after dangerous drugs or dangerous devices have been delivered.
(3) The secure storage facility has a means of indicating whether it has been entered after dangerous drugs or dangerous devices have been delivered.
(4) The pharmacy maintains written policies and procedures for the delivery of dangerous drugs and dangerous devices to a secure storage facility.
(**5**) The agent delivering dangerous drugs and dangerous devices pursuant to this subdivision leaves documents indicating the name and amount of each dangerous drug or dangerous device delivered in the secure storage facility.

The pharmacy shall be responsible for the dangerous drugs and dangerous devices delivered to the secure storage facility. The pharmacy shall also be responsible for obtaining

and maintainin g records relating to the delivery of dangerous drugs and dangerous devices to a secure storage facility.

(g) This section shall become operative on January 1, 2006.

§ 4081. Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory

(a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

(b) The owner, officer, and partner of a pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or designated representative-in-charge, for maintaining the records and inventory described in this section.

(c) The pharmacist-in-charge or representative-in-charge shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge or designated representative-in-charge had no knowledge, or in which he or she did not knowingly participate.

(d) This section shall become operative on January 1, 2006.

§ 4126.5. Persons or organizations that pharmacies may furnish with dangerous drugs; violations; offset of amounts due; definitions

(a) A pharmacy may furnish dangerous drugs only to the following, and only the following may receive dangerous drugs furnished by a pharmacy:

(1) A wholesaler owned or under common control by the wholesaler from whom the dangerous drug was acquired.

(2) The pharmaceutical manufacturer from whom the dangerous drug was acquired.

(3) A licensed wholesaler acting as a reverse distributor.

(4) Another pharmacy or wholesaler to alleviate a temporary shortage of a dangerous drug that could result in the denial of health care. A pharmacy furnishing dangerous drugs pursuant to this paragraph may only furnish a quantity sufficient to alleviate the temporary shortage.

(5) A patient or to another pharmacy pursuant to a prescription or as otherwise authorized by law.

(6) A health care provider that is not a pharmacy but that is authorized to purchase dangerous drugs.

(7) To another pharmacy under common control.

(b) Notwithstanding any other provision of law, a violation of this section ~~by either a pharmacy whose primary or sole business is filling prescriptions for patients of long-term care facilities or a person engaged in a prohibited transaction with a pharmacy whose primary or sole business is filling prescriptions for patients of long-term care facilities~~ may subject the person or persons who committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence pursuant to a citation issued by the board.

(c) Amounts due from any person under this section on or after January 1, 2005, shall be offset as provided under Section 12419.5 of the Government Code. Amounts received by the board under this section shall be deposited into the Pharmacy Board Contingent Fund.

(d) For purposes of this section, "common control" means the power to direct or cause the direction of the management and policies of another person whether by ownership, by voting rights, by contract, or by other means.

For purposes of subdivision (b) of this section and subdivision (s) of Section 4301, "long-term care facility" shall have the same meaning given the term in Section 1418 of the Health and Safety Code.

§ 4231. Requirements for renewal of pharmacist license; clock hours; exemption for new licensee

(a) The board shall not renew a pharmacist license unless the applicant submits proof satisfactory to the board that he or she has successfully completed 30 hours of approved courses of continuing pharmacy education during the two years preceding the application for renewal.

(b) Notwithstanding subdivision (a), the board shall not require completion of continuing education for the first renewal of a pharmacist license.

(c) If an applicant for renewal of a pharmacist license submits the renewal application and payment of the renewal fee but does not submit proof satisfactory to the board that the licensee has completed 30 hours of continuing pharmacy education, the board shall not renew the license and shall issue the applicant an inactive pharmacist license. A licensee with an inactive pharmacist license issued pursuant to this section may obtain an active pharmacist license by paying the renewal fees due and submitting satisfactory proof to the board that the licensee has completed 30 hours of continuing pharmacy education.

(d) If, as part of an investigation or audit conducted by the board, a pharmacist fails to provide documentation substantiating the completion of continuing education as required in subdivision (a) the board shall cancel the active pharmacist license and issue an inactive pharmacist license in its place. A licensee with an inactive pharmacist license issued pursuant to this section may obtain an active pharmacist license by paying the renewal fees due and submitting satisfactory proof to the board that the licensee has completed 30 hours of continuing pharmacy education.

§ 11165. Controlled Substance Utilization Review and Evaluation System: Establishment; Operations; Funding; Reporting to Legislature

(a) To assist law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II, Schedule III, and Schedule IV controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, and the Osteopathic Medical Board of California Contingent Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by all practitioners authorized to prescribe or dispense these controlled substances.

(b) The reporting of Schedule III and Schedule IV controlled substance prescriptions to CURES shall be contingent upon the availability of adequate funds from the Department of Justice. The Department of Justice may seek and use grant funds to pay the costs incurred from the reporting of controlled substance prescriptions to CURES. Funds shall not be appropriated from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, the Naturopathic Doctor's Fund, or the Osteopathic Medical Board of California Contingent Fund to pay the costs of reporting Schedule III and Schedule IV controlled substance prescriptions to CURES.

(c) CURES shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal persons or public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the Department of Justice, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the Department of Justice, for educational, peer review, statistical, or research purposes, provided that patient information, including any information that may identify the patient, is not compromised. Further, data disclosed to any individual or agency as described in this subdivision shall not be disclosed, sold, or transferred to any third party.

(d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, the dispensing pharmacy or clinic shall provide the following information to the Department of Justice on a weekly basis and in a format specified by the Department of Justice:

(1) Full name, address, and the telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and date of birth of the ultimate user.

(2) The prescriber's category of licensure and license number; federal controlled substance registration number; and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.

(3) Pharmacy prescription number, license number, and federal controlled substance registration number.

(4) NDC (National Drug Code) number of the controlled substance dispensed.

(5) Quantity of the controlled substance dispensed.

(6) ICD-9 (diagnosis code), if available.

(7) Number of refills ordered.

(8) Whether the drug was dispensed as a refill of a prescription or as a first-time request.

(9) Date of origin of the prescription.

(10) Date of dispensing of the prescription.

(e) This section shall become operative on January 1, 2005.

Attachment B-2

Omnibus Provisions Resulting From Recodification of Business and Professions Code Section 4052

Omnibus provisions resulting from the recodification of Business and Professions Code section 4052.

§ 733. Dispensing Prescription Drugs and Devices

(a) No licentiate shall obstruct a patient in obtaining a prescription drug or device that has been legally prescribed or ordered for that patient. A violation of this section constitutes unprofessional conduct by the licentiate and shall subject the licentiate to disciplinary or administrative action by his or her licensing agency.

(b) Notwithstanding any other provision of law, a licentiate shall dispense drugs and devices, as described in subdivision (a) of Section 4024, pursuant to a lawful order or prescription unless one of the following circumstances exists:

(1) Based solely on the licentiate's professional training and judgment, dispensing pursuant to the order or the prescription is contrary to law, or the licentiate determines that the prescribed drug or device would cause a harmful drug interaction or would otherwise adversely affect the patient's medical condition.

(2) The prescription drug or device is not in stock. If an order, other than an order described in Section 4019, or prescription cannot be dispensed because the drug or device is not in stock, the licentiate shall take one of the following actions:

(A) Immediately notify the patient and arrange for the drug or device to be delivered to the site or directly to the patient in a timely manner.

(B) Promptly transfer the prescription to another pharmacy known to stock the prescription drug or device that is near enough to the site from which the prescription or order is transferred, to ensure the patient has timely access to the drug or device.

(C) Return the prescription to the patient and refer the patient. The licentiate shall make a reasonable effort to refer the patient to a pharmacy that stocks the prescription drug or device that is near enough to the referring site to ensure that the patient has timely access to the drug or device.

(3) The licentiate refuses on ethical, moral, or religious grounds to dispense a drug or device pursuant to an order or prescription. A licentiate may decline to dispense a prescription drug or device on this basis only if the licentiate has previously notified his or her employer, in writing, of the drug or class of drugs to which he or she objects, and the licentiate's employer can, without creating undue hardship, provide a reasonable accommodation of the licentiate' s objection. The licentiate's employer shall establish protocols that ensure that the patient has timely access to the prescribed drug or device despite the licentiate's refusal to dispense the prescription or order. For purposes of this section, "reasonable accommodation" and "undue hardship" shall have the same meaning as applied to those terms pursuant to subdivision (l) of Section 12940 of the Government Code.

(c) For the purposes of this section, "prescription drug or device" has the same meaning as the definition in Section 4022.

(d) The provisions of this section shall apply to the drug therapy described in paragraph (8) of subdivision (a) of Section ~~4052~~ 4052.3.

(e) This section imposes no duty on a licentiate to dispense a drug or device pursuant to a prescription or order without payment for the drug or device, including payment directly by the patient or through a third party payer accepted by the licentiate or payment of any required copayment by the patient.

§ 4027. Skilled Nursing Facility – Intermediate Care Facility – Other Health Care Facilities

(a) As used in this chapter, the terms "skilled nursing facility," "intermediate care facility," and other references to health facilities shall be construed with respect to the definitions contained in Article 1 (commencing with Section 1250) of Chapter 2 of Division 2 of the Health and Safety Code.

(b) As used in paragraph (4) of subdivision (a) of Section ~~4052~~ 4052.1, "licensed health care facility" means a facility licensed pursuant to Article 1 (commencing with Section 1250) of Chapter 2 of Division 2 of the Health and Safety Code or a facility, as defined in Section 1250 of the Health and Safety Code, operated by a health care service plan licensed pursuant to Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code.

(c) As used in paragraph (5) of subdivision (a) of Section ~~4052~~ 4052.2, "health care facility" means a facility, other than a facility licensed under Division 2 (commencing with Section 1200) of the Health and Safety Code, that is owned or operated by a health care service plan licensed pursuant to Chapter 2.2 (commencing with Section 1340) of the Health and Safety Code, or by an organization under common ownership or control of the health care service plan; "licensed home health agency" means a private or public organization licensed by the State Department of Health Services pursuant to Chapter 8 (commencing with Section 1725) of Division 2 of the Health and Safety Code, as further defined in Section 1727 of the Health and Safety Code; and "licensed clinic" means a clinic licensed pursuant to Article 1 (commencing with Section 1200) of Chapter 1 of Division 2 of the Health and Safety Code.

(d) "Licensed health care facility" or "facility," as used in Section 4065, means a health facility licensed pursuant to Article 1 (commencing with Section 1250) of Chapter 2 of Division 2 of the Health and Safety Code or a facility that is owned or operated by a health care service plan licensed pursuant to Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code or by an organization under common ownership or control with the health care service plan.

§ 4040. Prescription; Content Requirements

(a) "Prescription" means an oral, written, or electronic transmission order that is both of the following:

(1) Given individually for the person or persons for whom ordered that includes all of the following:

(A) The name or names and address of the patient or patients.

(B) The name and quantity of the drug or device prescribed and the directions for use.

(C) The date of issue.

(D) Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed.

(E) A legible, clear notice of the condition for which the drug is being prescribed, if requested by the patient or patients.

(F) If in writing, signed by the prescriber issuing the order, or the certified nurse-midwife, nurse practitioner, physician assistant, or naturopathic doctor who issues a drug order pursuant to Section 2746.51, 2836.1, 3502.1, or 3640.5, respectively, or the pharmacist who issues a drug order pursuant to ~~either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of~~ Section ~~4052~~ 4052.2.

(2) Issued by a physician, dentist, optometrist, podiatrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7 or, if a drug order is issued pursuant to Section 2746.51, 2836.1, 3502.1, or 3460.5, by a certified nurse-midwife, nurse practitioner, physician assistant, or naturopathic doctor licensed in this state, or pursuant to ~~either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of~~ Section ~~4052~~ 4052.2 by a pharmacist licensed in this state.

(b) Notwithstanding subdivision (a), a written order of the prescriber for a dangerous drug, except for any Schedule II controlled substance, that contains at least the name and signature of the prescriber, the name and address of the patient in a manner consistent with paragraph (3) of subdivision (b) of Section 11164 of the Health and Safety Code, the name and quantity of the drug prescribed, directions for use, and the date of issue may be treated as a prescription by the dispensing pharmacist as long as any additional information required by subdivision (a) is readily retrievable in the pharmacy. In the event of a conflict between this subdivision and Section 11164 of the Health and Safety Code, Section 11164 of the Health and Safety Code shall prevail.

(c) "Electronic transmission prescription" includes both image and data prescriptions. "Electronic image transmission prescription" means any prescription order for which a facsimile of the order is received by a pharmacy from a licensed prescriber. "Electronic data transmission prescription" means any prescription order, other than an electronic image transmission prescription, that is electronically transmitted from a licensed prescriber to a pharmacy.

(d) The use of commonly used abbreviations shall not invalidate an otherwise valid prescription.

(e) Nothing in the amendments made to this section (formerly Section 4036) at the 1969 Regular Session of the Legislature shall be construed as expanding or limiting the right that a chiropractor, while acting within the scope of his or her license, may have to prescribe a device.

§ 4051. Conduct Limited to Pharmacist; Conduct Authorized by Pharmacist

(a) Except as otherwise provided in this chapter, it is unlawful for any person to manufacture, compound, furnish, sell, or dispense any dangerous drug or dangerous device, or to dispense or compound any prescription pursuant to Section 4040 of a prescriber unless he or she is a pharmacist under this chapter.

(b) Notwithstanding any other law, a pharmacist may authorize the initiation of a prescription, pursuant to Section ~~4052~~ 4052.2, and otherwise provide clinical advice or information or patient consultation if all of the following conditions are met:

(1) The clinical advice or information or patient consultation is provided to a health care professional or to a patient.

(2) The pharmacist has access to prescription, patient profile, or other relevant medical information for purposes of patient and clinical consultation and advice.

(3) Access to the information described in paragraph (2) is secure from unauthorized access and use.

§ 4060. Controlled Substance – Prescription Required, Exceptions

No person shall possess any controlled substance, except that furnished to a person upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7, or furnished pursuant to a drug order issued by a certified nurse-midwife pursuant to Section 2746.51, a nurse practitioner pursuant to Section 2836.1, a physician assistant pursuant to Section 3502.1, a naturopathic doctor pursuant to Section 3640.5, or a pharmacist pursuant to ~~either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of~~ Section ~~4052~~ 4052.2. This section shall not apply to the possession of any controlled substance by a manufacturer, wholesaler, pharmacy, pharmacist, physician, podiatrist, dentist, optometrist, veterinarian, naturopathic doctor, certified nurse-midwife, nurse practitioner, or physician assistant, when in stock in containers correctly labeled with the name and address of the supplier or producer. Nothing in this section authorizes a certified nurse-midwife, a nurse practitioner, a physician assistant, or a naturopathic doctor, to order his or her own stock of dangerous drugs and devices.

§ 4076. Prescription Container – Requirements for Labeling

(a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

(1) Except where the prescriber or the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol ~~pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of~~ Section ~~4052~~ 4052.2 orders otherwise, either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used. Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.

(2) The directions for the use of the drug.

(3) The name of the patient or patients.

(4) The name of the prescriber or, if applicable, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052.

(5) The date of issue.

(6) The name and address of the pharmacy, and prescription number or other means of identifying the prescription.

(7) The strength of the drug or drugs dispensed.

(8) The quantity of the drug or drugs dispensed.

(9) The expiration date of the effectiveness of the drug dispensed.

(10) The condition for which the drug was prescribed if requested by the patient and the condition is indicated on the prescription.

(11) (A) Commencing January 1, 2006, the physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules, except as follows:

(i) Prescriptions dispensed by a veterinarian.
(ii) An exemption from the requirements of this paragraph shall be granted to a new drug for the first 120 days that the drug is on the market and for the 90 days during which the national reference file has no description on file.
(iii) Dispensed medications for which no physical description exists in any commercially available database.
(B) This paragraph applies to outpatient pharmacies only.
(C) The information required by this paragraph may be printed on an auxiliary label that is affixed to the prescription container.
(D) This paragraph shall not become operative if the board, prior to January 1, 2006, adopts regulations that mandate the same labeling requirements set forth in this paragraph.

(b) If a pharmacist dispenses a prescribed drug by means of a unit dose medication system, as defined by administrative regulation, for a patient in a skilled nursing, intermediate care, or other health care facility, the requirements of this section will be satisfied if the unit dose medication system contains the aforementioned information or the information is otherwise readily available at the time of drug administration.

(c) If a pharmacist dispenses a dangerous drug or device in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include on individual unit dose containers for a specific patient, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052.

(d) If a pharmacist dispenses a prescription drug for use in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include the information required in paragraph (11) of subdivision (a) when the prescription drug is administered to a patient by a person licensed under the Medical Practice Act (Chapter 5 (commencing with Section 2000)), the Nursing Practice Act (Chapter 6 (commencing with Section 2700)), or the Vocational Nursing Practice Act (Chapter 6.5 (commencing with Section 2840)), who is acting within his or her scope of practice.

§ 4111. Restrictions on Prescriber Ownership

(a) Except as otherwise provided in subdivision (b), (d), or (e), the board shall not issue or renew a license to conduct a pharmacy to any of the following:
(1) A person or persons authorized to prescribe or write a prescription, as specified in Section 4040, in the State of California.
(2) A person or persons with whom a person or persons specified in paragraph (1) shares a community or other financial interest in the permit sought.
(3) Any corporation that is controlled by, or in which 10 percent or more of the stock is owned by a person or persons prohibited from pharmacy ownership by paragraph (1) or (2).

(b) Subdivision (a) shall not preclude the issuance of a permit for an inpatient hospital pharmacy to the owner of the hospital in which it is located.

(c) The board may require any information the board deems is reasonably necessary for the enforcement of this section.

(d) Subdivision (a) shall not preclude the issuance of a new or renewal license for a pharmacy to be owned or owned and operated by a person licensed on or before August 1, 1981, under the Knox-Keene Health Care Service Plan Act of 1975 (Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code) and qualified on or before August 1, 1981, under subsection (d) of Section 1310 of Title XIII of the federal Public Health Service Act, as amended, whose ownership includes persons defined pursuant to paragraphs (1) and (2) of subdivision (a).

(e) Subdivision (a) shall not preclude the issuance of a new or renewal license for a pharmacy to be owned or owned and operated by a pharmacist authorized to issue a drug order pursuant to subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section ~~4052~~ 4052.2.

§ 4174. Dispensing by Pharmacist Upon Order of a Nurse Practitioner

Notwithstanding any other provision of law, a pharmacist may dispense drugs or devices upon the drug order of a nurse practitioner functioning pursuant to Section 2836.1 or a certified nurse-midwife functioning pursuant to Section 2746.51, a drug order of a physician assistant functioning pursuant to Section 3502.1 or a naturopathic doctor functioning pursuant to Section 3640.5, or the order of a pharmacist acting under Section ~~4052~~ 4052.2.

Health and Safety Code Amendment

§ 11150 – Persons Authorized to Write or Issue a Prescription

No person other than a physician, dentist, podiatrist, or veterinarian, or pharmacist acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107 or within the scope of ~~either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of~~ Section ~~4052~~ 4052.2 of the Business and Professions Code, a registered nurse acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, a certified nursemidwife acting within the scope of Section 2746.51 of the Business and Professions Code, a nurse practitioner acting within the scope of Section 2836.1 of the Business and Professions Code, a physician assistant acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107 or Section 3502.1 of the Business and Professions Code, or an optometrist acting within the scope of Section 3041 of the Business and Professions Code, or an out-of-state prescriber acting pursuant to Section 4005 of the Business and Professions Code shall write or issue a prescription.

Attachment B-3

Omnibus Provisions for 2009

4013 Subscriber Alert

(a) By July 1, 2010 all board licensed facilities must join the board's e-mail notification list within 60 days of obtaining a license or at the time of license renewal.
(b) After July 1, 2010, any facility licensed by the board must update their e-mail address with the board's e-mail notification list within 30 days when a change in the e-mail address occurs.

§ 4101. ~~Persons in charge of pharmacy or exemptees~~ Pharmacist-in-charge; designated-representative-in-charge; termination of ~~employment~~ status; duty to notify board

(a) A pharmacist ~~who takes~~ may take charge of~~, or acts~~ and act as the pharmacist-in-charge of a pharmacy ~~or other entity licensed by the board~~ upon application by the pharmacy and approval by the board. Any pharmacist-in-charge who ~~terminates his or her employment at the pharmacy~~ ceases to act as the pharmacist-in-charge of the pharmacy ~~or other entity~~, shall notify the board in writing within 30 days of the ~~termination of employment~~ date of such change in status.

(b) ~~An exemptee~~ A designated representative or a pharmacist may take charge of and act as the designated representative-in-charge of a wholesaler or veterinary food drug-animal retailer upon application by the wholesaler or veterinary food drug-animal retailer and approval by the board. Any designated representative-in-charge who ~~terminates his or her employment~~ ceases to act as the designated representative-in-charge at that entity, shall notify the board in writing within 30 days of the ~~termination of employment~~ date of such change in status.

4112. Nonresident Pharmacy: Registration; Provision of Information to Board; Maintaining Records; Patient Consultation

(a) Any pharmacy located outside this state that ships, mails, or delivers, in any manner, controlled substances, dangerous drugs, or dangerous devices into this state shall be considered a nonresident pharmacy.
(b) A person may not act as a nonresident pharmacy unless he or she has obtained a license from the board. ~~All nonresident pharmacies shall register with the board~~. The board may register a nonresident pharmacy that is organized as a limited liability company in the state in which it is licensed.
(c) A nonresident pharmacy shall disclose to the board the location, names, and titles of (1) its agent for service of process in this state, (2) all principal corporate officers, if any, (3) all general partners, if any, and (4) all pharmacists who are dispensing controlled substances, dangerous drugs, or dangerous devices to residents of this state. A report containing this information shall be made on an annual basis and within 30 days after any change of office, corporate officer, partner, or pharmacist.

(d) All nonresident pharmacies shall comply with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is licensed as well as with all requests for information made by the board pursuant to this section. The nonresident pharmacy shall maintain, at all times, a valid unexpired license, permit, or registration to conduct the pharmacy in compliance with the laws of the state in which it is a resident. As a prerequisite to registering with the board, the nonresident pharmacy shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which it is located.
(e) All nonresident pharmacies shall maintain records of controlled substances, dangerous drugs, or dangerous devices dispensed to patients in this state so that the records are readily retrievable from the records of other drugs dispensed.
(f) Any pharmacy subject to this section shall, during its regular hours of operation, but not less than six days per week, and for a minimum of 40 hours per week, provide a toll-free telephone service to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. This toll-free telephone number shall be disclosed on a label affixed to each container of drugs dispensed to patients in this state.
(g) The board shall adopt regulations that apply the same requirements or standards for oral consultation to a nonresident pharmacy that operates pursuant to this section and ships, mails, or delivers any controlled substances, dangerous drugs, or dangerous devices to residents of this state, as are applied to an in-state pharmacy that operates pursuant to Section
4037 when the pharmacy ships, mails, or delivers any controlled substances, dangerous drugs, or dangerous devices to residents of this state. The board shall not adopt any regulations that require face-to-face consultation for a prescription that is shipped, mailed, or delivered to the patient. The regulations adopted pursuant to this subdivision shall not result in any unnecessary delay in patients receiving their medication.
(h) The registration fee shall be the fee specified in subdivision (a) of Section 4400.
(i) The registration requirements of this section shall apply only to a nonresident pharmacy that ships, mails, or delivers controlled substances, dangerous drugs, and dangerous devices into this state pursuant to a prescription.
(j) Nothing in this section shall be construed to authorize the dispensing of contact lenses by nonresident pharmacists except as provided by Section 4124.

§ 4113. Pharmacists-in-charge; ~~designation~~ approval; responsibilities; notifications

(a) Every pharmacy shall ~~designate a pharmacist-in-charge and within 30 days thereof, shall notify the board in writing of the identity and license number of that pharmacist and the date he or she was designated~~ be supervised or managed by a pharmacist-in-charge. As part of its initial application for a license, and for each renewal, each pharmacy shall, on a form designed by the board, provide identifying information and the California license number for a pharmacist proposed to serve as the pharmacist-in-charge. The proposed pharmacist-in-charge shall be subject to approval by the board. The board shall not issue or renew a pharmacy license without identification of an approved pharmacist-in-charge for the pharmacy.

(b) The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

(c) Every pharmacy shall notify the board in writing, on a form designed by the board, within 30 days of the date when a ~~pharmacist ceases to be a~~ pharmacist-in-charge ceases to act as pharmacist-in-charge, and shall on the same form propose another pharmacist to take over as pharmacist-in-charge. The proposed replacement pharmacist-in-charge shall be subject to approval by the board. If disapproved, the pharmacy shall propose another replacement within 15 days of the date of disapproval, and shall continue to name proposed replacements until a pharmacist-in-charge is approved by the board.

(d) If a pharmacy is unable, in the exercise of reasonable diligence, to identify within 30 days a permanent replacement pharmacist-in-charge to propose to the board on the notification form, the pharmacy may instead supply on that form the name of any pharmacist who is an employee, officer or administrator of the pharmacy or the entity which owns the pharmacy and who is actively involved in the management of the pharmacy on a daily basis, to act as the interim pharmacist-in-charge for a period not to exceed 120 days. The pharmacy, or the entity which owns the pharmacy, shall be prepared during normal business hours to provide a representative of the board with the name of the interim pharmacist-in-charge, with documentation of the active involvement of the interim pharmacist-in-charge in the daily management of the pharmacy, and with documentation of the pharmacy's good faith efforts prior to naming the interim pharmacist-in-charge to obtain a permanent pharmacist-in-charge. By no later than 120 days following the identification of the interim pharmacist-in-charge, the pharmacy shall propose to the board the name of a pharmacist to serve as the permanent pharmacist-in-charge. The proposed permanent pharmacist-in-charge shall be subject to approval by the board. If disapproved, the pharmacy shall propose another replacement within 15 days of the date of disapproval, and shall continue to name proposed replacements until a pharmacist-in-charge is approved by the board.

§4146 Sharps Take Back

A pharmacy may accept the return of needles and syringes from the public if contained in a sharps container as defined by Health and Safety Code section 117750.

§ 4160. Wholesaler Licenses

(a) A person may not act as a wholesaler of any dangerous drug or dangerous device unless he or she has obtained a license from the board.

(b) Upon approval by the board and the payment of the required fee, the board shall issue a license to the applicant.

(c) A separate license shall be required for each place of business owned or operated by a wholesaler. Each license shall be renewed annually and shall not be transferable.

(d) ~~The board shall not issue or renew a wholesaler license until the wholesaler identifies a designated representative-in-charge and notifies the board in writing of the identity and license number of that designated representative.~~ Every wholesaler shall be supervised or managed by a designated representative-in-charge. The designated representative-in-charge shall be responsible for the wholesaler's compliance with state and federal laws governing wholesalers. As part of its initial application for a license, and for each

renewal, each wholesaler shall, on a form designed by the board, provide identifying information and the California license number for a designated representative or pharmacist proposed to serve as the designated representative-in-charge. The proposed designated representative-in-charge shall be subject to approval by the board. The board shall not issue or renew a wholesaler license without identification of an approved designated representative-in-charge for the wholesaler.

(e) ~~A wholesaler shall identify and notify the board of a new designated representative-in-charge within 30 days of the date that the prior designated representative-in-charge ceases to be the designated representative-in-charge. A pharmacist may be identified as the designated representative-in-charge.~~ Every wholesaler shall notify the board in writing, on a form designed by the board, within 30 days of the date when a designated representative-in-charge ceases to act as designated representative-in-charge, and shall on the same form propose another designated representative or pharmacist to take over as designated representative-in-charge. The proposed replacement designated representative-in-charge shall be subject to approval by the board. If disapproved, the wholesaler shall propose another replacement within 15 days of the date of disapproval, and shall continue to name proposed replacements until a designated representative-in-charge is approved by the board.

(~~e~~ f) A drug manufacturer licensed by the Food and Drug Administration or licensed pursuant to Section 111615 of the Health and Safety Code that only distributes dangerous drugs and dangerous devices of its own manufacture is exempt from this section and Section 4161.

(~~f~~ g) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A temporary license fee shall be ~~five hundred fifty dollars ($550)~~ six hundred dollars ($600) ~~or another amount established by the board not to exceed the annual fee for renewal of a license to compound injectable sterile drug products~~. When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, subject to terms and conditions that the board deems necessary. If the board determines that a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon either personal service of the notice of termination upon the licenseholder or service by certified mail, return receipt requested, at the licenseholder's address of record with the board, whichever occurs first. Neither for purposes of retaining a temporary license, nor for purposes of any disciplinary or license denial proceeding before the board, shall the temporary licenseholder be deemed to have a vested property right or interest in the license.

~~(g) This section shall become operative on January 1, 2006.~~

§ 4196. Veterinary Food-Animal Drug Retailer Licenses; persons allowed in areas where drugs stored, possessed, or repacked

(a) No person shall conduct a veterinary food-animal drug retailer in the State of California unless he or she has obtained a license from the board. A license shall be required for each veterinary food-animal drug retailer owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a veterinary food-animal drug retailer in more than one location. The license

shall be renewed annually and shall not be transferable.

(b) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A temporary license fee shall be fixed by the board at an amount not to exceed the annual fee for renewal of a license to conduct a veterinary food-animal drug retailer.

(c) No person other than a pharmacist, an intern pharmacist, a designated representative, an authorized officer of the law, or a person authorized to prescribe, shall be permitted in that area, place, or premises described in the permit issued by the board pursuant to Section 4041, wherein veterinary food-animal drugs are stored, possessed, or repacked. A pharmacist or designated representative shall be responsible for any individual who enters the veterinary food-animal drug retailer for the purpose of performing clerical, inventory control, housekeeping, delivery, maintenance, or similar functions relating to the veterinary food-animal drug retailer.

(d) ~~The board shall not issue or renew a veterinary food-animal retailer license until the veterinary food-animal drug retailer identifies a designated representative-in-charge and notifies the board in writing of the identity and license number of that designated representative.~~ Every veterinary food-animal drug retailer shall be supervised or managed by a designated representative-in-charge. The designated representative-in-charge shall be responsible for the veterinary food-animal drug retailer's compliance with state and federal laws governing veterinary food-animal drug retailers. As part of its initial application for a license, and for each renewal, each veterinary food-animal drug retailer shall, on a form designed by the board, provide identifying information and the California license number for a designated representative or pharmacist proposed to serve as the designated representative-in-charge. The proposed designated representative-in-charge shall be subject to approval by the board. The board shall not issue or renew a veterinary food-animal drug retailer license without identification of an approved designated representative-in-charge for the veterinary food-animal drug retailer.

(e) ~~Each veterinary food-animal drug retailer shall identify, and notify the board of, a new designated representative-in-charge within 30 days of the date that the prior designated representative-in-charge ceases to be the designated representative-in-charge. A pharmacist may be identified as the designated representative-in-charge.~~ Every veterinary food-animal drug retailer shall notify the board in writing, on a form designed by the board, within 30 days of the date when a designated representative-in-charge who ceases to act as designated representative-in-charge, and shall on the same form propose another designated representative or pharmacist to take over as designated representative-in-charge. The proposed replacement designated representative-in-charge shall be subject to approval by the board. If disapproved, the veterinary food-animal drug retailer shall propose another replacement within 15 days of the date of disapproval, and shall continue to name proposed replacements until a designated representative-in-charge is approved by the board.

(e f) For purposes of this section, designated representative-in-charge means a person granted a designated representative license pursuant to Section 4053, or a registered pharmacist, who is the supervisor or manager of the facility.

regarding the conduct of the pharmacist or intern pharmacist, that information may serve as a basis for discipline or other enforcement by the board.

(c) A pharmacist or intern pharmacist enrolled in the pharmacists recovery program shall be responsible to pay an administrative co-pay of $100 monthly to cover a portion of the administrative costs borne by the board to contract for these services.

(1) This fee may be waived, reduced, or deferred by the board or its designee if the participant demonstrates a financial hardship.

§ 4200.1. Retaking Examinations; Set Limits; Requirements

4200.1. (a) Notwithstanding Section 135, an applicant may take the North American Pharmacist Licensure Examination four times, and may take the California Practice Standards and Jurisprudence Examination for Pharmacists four times.

(b) Notwithstanding Section 135, an applicant may take the North American Pharmacist Licensure Examination and the California Practice Standards and Jurisprudence Examination for Pharmacists four additional times each if he or she successfully completes, at minimum, 16 additional semester units of education in pharmacy as approved by the board.

(c) The applicant shall comply with the requirements of Section 4200 for each application for reexamination made pursuant to subdivision (b).

(d) An applicant may use the same coursework to satisfy the additional educational requirement for each examination under subdivision (b), if the coursework was completed within 12 months of the date of his or her application for reexamination.

(e) For purposes of this section, the board shall treat each failing score on the pharmacist licensure examination administered by the board prior to January 1, 2004, as a failing score on both the North American Pharmacist Licensure Examination and the California Practice Standards and Jurisprudence Examination for Pharmacists.

(f) From January 1, 2004, to July 1, 2008, inclusive, the board shall collect data on the applicants who are admitted to, and take, the licensure examinations required by Section 4200. The board shall report to the Joint Committee on Boards, Commissions, and Consumer Protection before September 1, 2008, regarding the impact on those applicants of the examination limitations imposed by this section. The report shall include, but not be limited to, the following information:

(1) The number of applicants taking the examination and the number who fail the examination for the fourth time.

(2) The number of applicants who, after failing the examination for the fourth time, complete a pharmacy studies program in California or another state to satisfy the requirements of this section and who apply to take the licensure examination required by Section 4200.

(3) To the extent possible, the school from which the applicant graduated and the school's location and the pass/fail rates on the examination for each school.

~~(g) This section shall remain in effect only until January 1, 2010, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2010, deletes or extends that date.~~

Attachment B-4

Immunization Proposal

Amend Business and Professions Code section 4052 and Add section 4052.8
ACIP Adult and Adolescent Immunization Schedules
Fact Sheets

4052. (a) Notwithstanding any other provision of law, a pharmacist may:

1) Furnish a reasonable quantity of compounded drug product to a prescriber for office use by the prescriber.

2) Transmit a valid prescription to another pharmacist.

3) Administer, orally or topically, drugs and biologicals pursuant to a prescriber's order.

4) Perform procedures or functions in a licensed health care facility as authorized by Section 4052.1.

5) Perform procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, as authorized by Section 4052.2.

6) Manufacture, measure, fit to the patient, or sell and repair dangerous devices or furnish instructions to the patient or the patient's representative concerning the use of those devices.

7) Provide consultation to patients and professional information, including clinical or pharmacological information, advice, or consultation to other health care professionals.

8) Furnish emergency contraception drug therapy as authorized by Section 4052.3.

9) Initiate and administer immunizations ~~pursuant to a protocol with a prescriber~~ as authorized by Section 4052.8.

(b) A pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy pursuant to this section shall personally register with the federal Drug Enforcement Administration.

(c) Nothing in this section shall affect the requirements of existing law relating to maintaining the confidentiality of medical records.

(d) Nothing in this section shall affect the requirements of existing law relating to the licensing of a health care facility.

4052.8 (a) A pharmacist may initiate and administer immunizations pursuant to a protocol with a prescriber. A pharmacist may also initiate and administer immunizations pursuant to the current Recommended Adult (19+ years) and Adolescent (7-18 years) Immunization Schedules, provided by the Centers for Disease Control and Prevention (CDC) pursuant to published recommendations of the CDC Advisory Committee on Immunization Practices (ACIP).

(b) Prior to initiating and administering an immunization pursuant to this section, a pharmacist shall have completed the American Pharmacists Association pharmacy-based immunization certificate program or another pharmacy-based immunization training certificate program endorsed by the Centers for Disease Control and Prevention or the American Council of Pharmaceutical Education.

(c) A pharmacist initiating and administering any immunization pursuant to this section shall also complete 3 hours of immunization-related continuing education coursework annually. Failure at any time to meet this requirement shall, in addition to any other sanctions, require the pharmacist to re-take the training identified in subdivision (b) prior to administration of any further immunization(s).

(d) A pharmacist shall at all times maintain current Basic Life Support certification.

(e) At the time of administration of an immunization, the pharmacist shall:

(1) Provide the patient or patient's agent with the appropriate Vaccine Information Statement for each immunization administered; and

(2) Provide documentation of administration of the immunization to the patient and patient's physician or primary care provider, if one can be identified.

(f) Any pharmacist initiating and administering vaccines pursuant to this section may initiate and administer epinephrine by injection for severe allergic reactions.

(g) Any adverse event shall be reported to the Vaccine Adverse Event Reporting System within the U.S. Department of Health and Human Services.

(h) The pharmacist shall maintain an immunization administration record, which includes, but is not limited to, the name of the vaccine, expiration date, date of administration, manufacturer and lot number, administration site and route, Vaccine Information Statement date, and the name and title of the person administering, for the longer of the following periods:

(1) Ten years from the date of administration; or

(2) If less than 18 years at the time of administration, three years beyond the patient's eighteenth birthday.

(i) Upon receipt of a vaccine as authorized by this section, a pharmacist is responsible to assure that proper vaccine temperatures are maintained during subsequent storage and handling to preserve potency.

Recommended Adult Immunization Schedule

Note: These recommendations must be read with the footnotes that follow.

Figure 1. Recommended adult immunization schedule, by vaccine and age group United States, October 2007 – September 2008

VACCINE ▼ AGE GROUP ▶	19–49 years	50–64 years	≥65 years
Tetanus, diphtheria, pertussis (Td/Tdap)[1,*]	1 dose Td booster every 10 yrs Substitute 1 dose of Tdap for Td		
Human papillomavirus (HPV)[2,*]	3 doses females (0, 2, 6 mos)		
Measles, mumps, rubella (MMR)[3,*]	1 or 2 doses	1 dose	
Varicella[4,*]	2 doses (0, 4–8 wks)		
Influenza[5,*]	1 dose annually		
Pneumococcal (polysaccharide)[6,7]	1–2 doses		1 dose
Hepatitis A[8,*]	2 doses (0, 6–12 mos or 0, 6–18 mos)		
Hepatitis B[9,*]	3 doses (0, 1–2, 4–6 mos)		
Meningococcal[10,*]	1 or more doses		
Zoster[11]			1 dose

*Covered by the Vaccine Injury Compensation Program.

For all persons in this category who meet the age requirements and who lack evidence of immunity (e.g., lack documentation of vaccination or have no evidence of prior infection)

Recommended if some other risk factor is present (e.g., on the basis of medical, occupational, lifestyle, or other indications)

Report all clinically significant postvaccination reactions to the Vaccine Adverse Event Reporting System (VAERS). Reporting forms and instructions on filing a VAERS report are available at www.vaers.hhs.gov or by telephone, 800-822-7967.

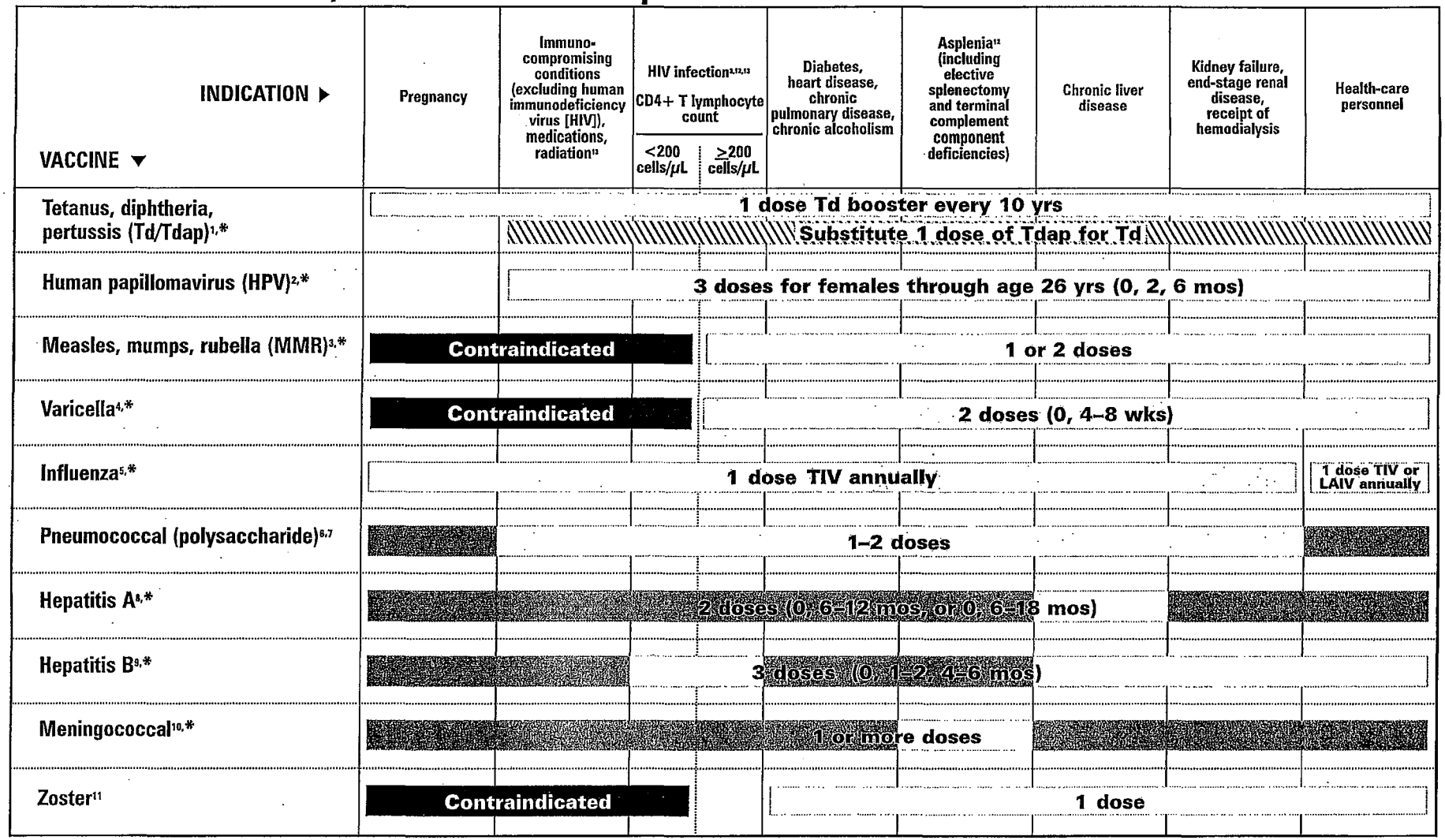
Information on how to file a Vaccine Injury Compensation Program claim is available at www.hrsa.gov/vaccinecompensation or by telephone, 800-338-2382. To file a claim for vaccine injury, contact the U.S. Court of Federal Claims, 717 Madison Place, N.W., Washington, D.C. 20005; telephone, 202-357-6400.

Additional information about the vaccines in this schedule, extent of available data, and contraindications for vaccination is also available at www.cdc.gov/vaccines or from the CDC-INFO Contact Center at 800-CDC-INFO (800-232-4636) in English and Spanish, 24 hours a day, 7 days a week.

Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.

CS115143

Figure 2. Vaccines that might be indicated for adults based on medical and other indications United States, October 2007 – September 2008



*Covered by the Vaccine Injury Compensation Program.

For all persons in this category who meet the age requirements and who lack evidence of immunity (e.g., lack documentation of vaccination or have no evidence of prior infection)

Recommended if some other risk factor is present (e.g., on the basis of medical, occupational, lifestyle, or other indications)

These schedules indicate the recommended age groups and medical indications for which administration of currently licensed vaccines is commonly indicated for adults ages 19 years and older, as of October 1, 2007. Licensed combination vaccines may be used whenever any components of the combination are indicated and when the vaccine's other components are not contraindicated. For detailed recommendations on all vaccines, including those used primarily for travelers or that are issued during the year, consult the manufacturers' package inserts and the complete statements from the Advisory Committee on Immunization Practices (www.cdc.gov/vaccines/pubs/acip-list.htm).

The recommendations in this schedule were approved by the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP), the American Academy of Family Physicians (AAFP), the American College of Obstetricians and Gynecologists (ACOG), and the American College of Physicians (ACP).

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION

Footnotes

Recommended Adult Immunization Schedule · United States, October 2007 – September 2008

For complete statements by the Advisory Committee on Immunization Practices (ACIP), visit www.cdc.gov/vaccines/pubs/ACIP-list.htm.

1. Tetanus, diphtheria, and acellular pertussis (Td/Tdap) vaccination

Tdap should replace a single dose of Td for adults aged <65 years who have not previously received a dose of Tdap. Only one of two Tdap products (Adacel®[sanofi pasteur]) is licensed for use in adults.

Adults with uncertain histories of a complete primary vaccination series with tetanus and diphtheria toxoid–containing vaccines should begin or complete a primary vaccination series. A primary series for adults is 3 doses of tetanus and diphtheria toxoid–containing vaccines; administer the first 2 doses at least 4 weeks apart and the third dose 6–12 months after the second. However, Tdap can substitute for any one of the doses of Td in the 3-dose primary series. The booster dose of tetanus and diphtheria toxoid–containing vaccine should be administered to adults who have completed a primary series and if the last vaccination was received ≥10 years previously. Tdap or Td vaccine may be used, as indicated.

If the person is pregnant and received the last Td vaccination ≥10 years previously, administer Td during the second or third trimester; if the person received the last Td vaccination in <10 years, administer Tdap during the immediate postpartum period. A one-time administration of 1 dose of Tdap with an interval as short as 2 years from a previous Td vaccination is recommended for postpartum women, close contacts of infants aged <12 months, and all health-care workers with direct patient contact. In certain situations, Td can be deferred during pregnancy and Tdap substituted in the immediate postpartum period, or Tdap can be administered instead of Td to a pregnant woman after an informed discussion with the woman.

Consult the ACIP statement for recommendations for administering Td as prophylaxis in wound management.

2. Human papillomavirus (HPV) vaccination

HPV vaccination is recommended for all females aged ≤26 years who have not completed the vaccine series. History of genital warts, abnormal Papanicolaou test, or positive HPV DNA test is not evidence of prior infection with all vaccine HPV types; HPV vaccination is still recommended for these persons.

Ideally, vaccine should be administered before potential exposure to HPV through sexual activity; however, females who are sexually active should still be vaccinated. Sexually active females who have not been infected with any of the HPV vaccine types receive the full benefit of the vaccination. Vaccination is less beneficial for females who have already been infected with one or more of the HPV vaccine types.

A complete series consists of 3 doses. The second dose should be administered 2 months after the first dose; the third dose should be administered 6 months after the first dose.

Although HPV vaccination is not specifically recommended for females with the medical indications described in Figure 2, "Vaccines that might be indicated for adults based on medical and other indications," it is not a live-virus vaccine and can be administered. However, immune response and vaccine efficacy might be less than in persons who do not have the medical indications described or who are immunocompetent.

3. Measles, mumps, rubella (MMR) vaccination

Measles component: Adults born before 1957 can be considered immune to measles. Adults born during or after 1957 should receive ≥1 dose of MMR unless they have a medical contraindication, documentation of ≥1 dose, history of measles based on health-care provider diagnosis, or laboratory evidence of immunity.

A second dose of MMR is recommended for adults who 1) have been recently exposed to measles or are in an outbreak setting; 2) have been previously vaccinated with killed measles vaccine; 3) have been vaccinated with an unknown type of measles vaccine during 1963–1967; 4) are students in postsecondary educational institutions; 5) work in a health-care facility; or 6) plan to travel internationally.

Mumps component: Adults born before 1957 can generally be considered immune to mumps. Adults born during or after 1957 should receive 1 dose of MMR unless they have a medical contraindication, history of mumps based on health-care provider diagnosis, or laboratory evidence of immunity.

A second dose of MMR is recommended for adults who 1) are in an age group that is affected during a mumps outbreak; 2) are students in postsecondary educational institutions; 3) work in a health-care facility; or 4) plan to travel internationally. For unvaccinated health-care workers born before 1957 who do not have other evidence of mumps immunity, consider administering 1 dose on a routine basis and strongly consider administering a second dose during an outbreak.

Rubella component: Administer 1 dose of MMR vaccine to women whose rubella vaccination history is unreliable or who lack laboratory evidence of immunity. For women of childbearing age, regardless of birth year, routinely determine rubella immunity and counsel women regarding congenital rubella syndrome. Women who do not have evidence of immunity should receive MMR vaccine upon completion or termination of pregnancy and before discharge from the health-care facility.

4. Varicella vaccination

All adults without evidence of immunity to varicella should receive 2 doses of single-antigen varicella vaccine unless they have a medical contraindication. Special consideration should be given to those who 1) have close contact with persons at high risk for severe disease (e.g., health-care personnel and family contacts of immunocompromised persons) or 2) are at high risk for exposure or transmission (e.g., teachers; child care employees; residents and staff members of institutional settings, including correctional institutions; college students; military personnel; adolescents and adults living in households with children; nonpregnant women of childbearing age; and international travelers).

Evidence of immunity to varicella in adults includes any of the following: 1) documentation of 2 doses of varicella vaccine at least 4 weeks apart; 2) U.S.-born before 1980 (although for health-care personnel and pregnant women birth before 1980 should not be considered evidence of immunity); 3) history of varicella based on diagnosis or verification of varicella by a health-care provider (for a patient reporting a history of or presenting with an atypical case, a mild case, or both, health-care providers should seek either an epidemiologic link with a typical varicella case or to a laboratory-confirmed case or evidence of laboratory confirmation, if it was performed at the time of acute disease); 4) history of herpes zoster based on health-care provider diagnosis; or 5) laboratory evidence of immunity or laboratory confirmation of disease.

Assess pregnant women for evidence of varicella immunity. Women who do not have evidence of immunity should receive the first dose of varicella vaccine upon completion or termination of pregnancy and before discharge from the health-care facility. The second dose should be administered 4–8 weeks after the first dose.

5. Influenza vaccination

Medical indications: Chronic disorders of the cardiovascular or pulmonary systems, including asthma; chronic metabolic diseases, including diabetes mellitus, renal or hepatic dysfunction, hemoglobinopathies, or immunosuppression (including immunosuppression caused by medications or human immunodeficiency virus [HIV]); any condition that compromises respiratory function or the handling of respiratory secretions or that can increase the risk of aspiration (e.g., cognitive dysfunction, spinal cord injury, or seizure disorder or other neuromuscular disorder); and pregnancy during the influenza season. No data exist on the risk for severe or complicated influenza disease among persons with asplenia; however, influenza is a risk factor for secondary bacterial infections that can cause severe disease among persons with asplenia.

Occupational indications: Health-care personnel and employees of long-term care and assisted-living facilities.

Other indications: Residents of nursing homes and other long-term care and assisted-living facilities; persons likely to transmit influenza to persons at high risk (e.g., in-home household contacts and caregivers of children aged 0–59 months, or persons of all ages with high-risk conditions); and anyone who would like to be vaccinated. Healthy, nonpregnant adults aged ≤49 years without high-risk medical conditions who are not contacts of severely immunocompromised persons in special care units can receive either intranasally administered live, attenuated influenza vaccine (FluMist®) or inactivated vaccine. Other persons should receive the inactivated vaccine.

6. Pneumococcal polysaccharide vaccination

Medical indications: Chronic pulmonary disease (excluding asthma); chronic cardiovascular diseases; diabetes mellitus; chronic liver diseases, including liver disease as a result of alcohol abuse (e.g., cirrhosis); chronic alcoholism, chronic renal failure or nephrotic syndrome; functional or anatomic asplenia (e.g., sickle cell disease or splenectomy [if elective splenectomy is planned, vaccinate at least 2 weeks before surgery]); immunosuppressive conditions; and cochlear implants and cerebrospinal fluid leaks. Vaccinate as close to HIV diagnosis as possible.

Other indications: Alaska Natives and certain American Indian populations and residents of nursing homes or other long-term care facilities.

7. Revaccination with pneumococcal polysaccharide vaccine

One-time revaccination after 5 years for persons with chronic renal failure or nephrotic syndrome; functional or anatomic asplenia (e.g., sickle cell disease or splenectomy); or immunosuppressive conditions. For persons aged ≥65 years, one-time revaccination if they were vaccinated ≥5 years previously and were aged <65 years at the time of primary vaccination.

8. Hepatitis A vaccination

Medical indications: Persons with chronic liver disease and persons who receive clotting factor concentrates.

Behavioral indications: Men who have sex with men and persons who use illegal drugs.

Occupational indications: Persons working with hepatitis A virus (HAV)–infected primates or with HAV in a research laboratory setting.

Other indications: Persons traveling to or working in countries that have high or intermediate endemicity of hepatitis A (a list of countries is available at wwwn.cdc.gov/travel/contentdiseases.aspx) and any person seeking protection from HAV infection.

Single-antigen vaccine formulations should be administered in a 2-dose schedule at either 0 and 6–12 months (Havrix®), or 0 and 6–18 months (Vaqta®). If the combined hepatitis A and hepatitis B vaccine (Twinrix®) is used, administer 3 doses at 0, 1, and 6 months.

9. Hepatitis B vaccination

Medical indications: Persons with end-stage renal disease, including patients receiving hemodialysis; persons seeking evaluation or treatment for a sexually transmitted disease (STD); persons with HIV infection; and persons with chronic liver disease.

Occupational indications: Health-care personnel and public-safety workers who are exposed to blood or other potentially infectious body fluids.

Behavioral indications: Sexually active persons who are not in a long-term, mutually monogamous relationship (e.g., persons with more than 1 sex partner during the previous 6 months); current or recent injection-drug users; and men who have sex with men.

Other indications: Household contacts and sex partners of persons with chronic hepatitis B virus (HBV) infection; clients and staff members of institutions for persons with developmental disabilities; international travelers to countries with high or intermediate prevalence of chronic HBV infection (a list of countries is available at wwwn.cdc.gov/travel/contentdiseases.aspx); and any adult seeking protection from HBV infection.

Settings where hepatitis B vaccination is recommended for all adults: STD treatment facilities; HIV testing and treatment facilities; facilities providing drug-abuse treatment and prevention services; health-care settings targeting services to injection-drug users or men who have sex with men; correctional facilities; end-stage renal disease programs and facilities for chronic hemodialysis patients; and institutions and nonresidential daycare facilities for persons with developmental disabilities.

Special formulation indications: For adult patients receiving hemodialysis and other immunocompromised adults, 1 dose of 40 μg/mL (Recombivax HB®), or 2 doses of 20 μg/mL (Engerix-B®) administered simultaneously.

10.Meningococcal vaccination

Medical indications: Adults with anatomic or functional asplenia, or terminal complement component deficiencies.

Other indications: First-year college students living in dormitories; microbiologists who are routinely exposed to isolates of *Neisseria meningitidis*; military recruits; and persons who travel to or live in countries in which meningococcal disease is hyperendemic or epidemic (e.g., the "meningitis belt" of sub-Saharan Africa during the dry season [December–June]), particularly if their contact with local populations will be prolonged. Vaccination is required by the government of Saudi Arabia for all travelers to Mecca during the annual Hajj.

Meningococcal conjugate vaccine is preferred for adults with any of the preceding indications who are aged ≤55 years, although meningococcal polysaccharide vaccine (MPSV4) is an acceptable alternative. Revaccination after 3–5 years might be indicated for adults previously vaccinated with MPSV4 who remain at increased risk for infection (e.g., persons residing in areas in which disease is epidemic).

11.Herpes zoster vaccination

A single dose of zoster vaccine is recommended for adults aged ≥60 years regardless of whether they report a prior episode of herpes zoster. Persons with chronic medical conditions may be vaccinated unless a contraindication or precaution exists for their condition.

12.Selected conditions for which *Haemophilus influenzae* type b (Hib) vaccine may be used

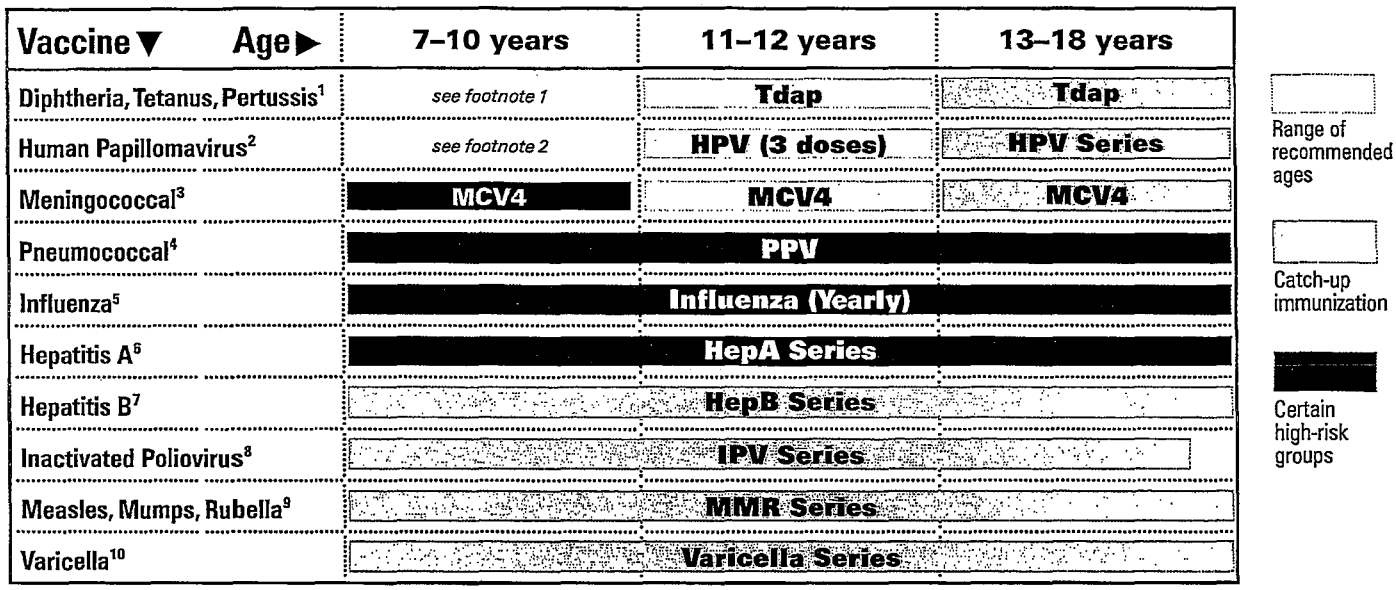
Hib conjugate vaccines are licensed for children aged 6 weeks–71 months. No efficacy data are available on which to base a recommendation concerning use of Hib vaccine for older children and adults with the chronic conditions associated with an increased risk for Hib disease. However, studies suggest good immunogenicity in patients who have sickle cell disease, leukemia, or HIV infection or who have had splenectomies; administering vaccine to these patients is not contraindicated.

13.Immunocompromising conditions

Inactivated vaccines are generally acceptable (e.g., pneumococcal, meningococcal, and influenza [trivalent inactivated influenza vaccine]), and live vaccines generally are avoided in persons with immune deficiencies or immune suppressive conditions. Information on specific conditions is available at www.cdc.gov/vaccines/pubs/acip-list.htm.

Recommended Immunization Schedule for Persons Aged 7–18 Years—UNITED STATES • 2008

For those who fall behind or start late, see the green bars and the catch-up schedule



This schedule indicates the recommended ages for routine administration of currently licensed childhood vaccines, as of December 1, 2007, for children aged 7–18 years. Additional information is available at **www.cdc.gov/vaccines/recs/schedules.** Any dose not administered at the recommended age should be administered at any subsequent visit, when indicated and feasible. Additional vaccines may be licensed and recommended during the year. Licensed combination vaccines may be used whenever any components of the combination are indicated and other components of the vaccine are not contraindicated and if approved by the Food and Drug Administration for that dose of the series. Providers should consult the respective Advisory Committee on Immunization Practices statement for detailed recommendations, including for **high risk conditions: http://www.cdc.gov/vaccines/pubs/ACIP-list.htm.** Clinically significant adverse events that follow immunization should be reported to the Vaccine Adverse Event Reporting System (VAERS). Guidance about how to obtain and complete a VAERS form is available at **www.vaers.hhs.gov** or by telephone, **800-822-7967.**

1. Tetanus and diphtheria toxoids and acellular pertussis vaccine (Tdap). *(Minimum age: 10 years for BOOSTRIX® and 11 years for ADACEL™)*
- Administer at age 11–12 years for those who have completed the recommended childhood DTP/DTaP vaccination series and have not received a tetanus and diphtheria toxoids (Td) booster dose.
- 13–18-year-olds who missed the 11–12 year Tdap or received Td only are encouraged to receive one dose of Tdap 5 years after the last Td/DTaP dose.

2. Human papillomavirus vaccine (HPV). *(Minimum age: 9 years)*
- Administer the first dose of the HPV vaccine series to females at age 11–12 years.
- Administer the second dose 2 months after the first dose and the third dose 6 months after the first dose.
- Administer the HPV vaccine series to females at age 13–18 years if not previously vaccinated.

3. Meningococcal vaccine.
- Administer MCV4 at age 11–12 years and at age 13–18 years if not previously vaccinated. MPSV4 is an acceptable alternative.
- Administer MCV4 to previously unvaccinated college freshmen living in dormitories.
- MCV4 is recommended for children aged 2–10 years with terminal complement deficiencies or anatomic or functional asplenia and certain other high-risk groups.
- Persons who received MPSV4 3 or more years previously and remain at increased risk for meningococcal disease should be vaccinated with MCV4.

4. Pneumococcal polysaccharide vaccine (PPV).
- Administer PPV to certain high-risk groups.

5. Influenza vaccine.
- Administer annually to all close contacts of children aged 0–59 months.
- Administer annually to persons with certain risk factors, health-care workers, and other persons (including household members) in close contact with persons in groups at higher risk.
- Administer 2 doses (separated by 4 weeks or longer) to children younger than 9 years who are receiving influenza vaccine for the first time or who were vaccinated for the first time last season but only received one dose.
- For healthy nonpregnant persons (those who do not have underlying medical conditions that predispose them to influenza complications) ages 2–49 years, either LAIV or TIV may be used.

6. Hepatitis A vaccine (HepA).
- Administer the 2 doses in the series at least 6 months apart.
- HepA is recommended for certain other groups of children, including in areas where vaccination programs target older children.

7. Hepatitis B vaccine (HepB).
- Administer the 3-dose series to those who were not previously vaccinated.
- A 2-dose series of Recombivax HB® is licensed for children aged 11–15 years.

8. Inactivated poliovirus vaccine (IPV).
- For children who received an all-IPV or all-oral poliovirus (OPV) series, a fourth dose is not necessary if the third dose was administered at age 4 years or older.
- If both OPV and IPV were administered as part of a series, a total of 4 doses should be administered, regardless of the child's current age.

9. Measles, mumps, and rubella vaccine (MMR).
- If not previously vaccinated, administer 2 doses of MMR during any visit, with 4 or more weeks between the doses.

10. Varicella vaccine.
- Administer 2 doses of varicella vaccine to persons younger than 13 years of age at least 3 months apart. Do not repeat the second dose if administered 28 or more days following the first dose.
- Administer 2 doses of varicella vaccine to persons aged 13 years or older at least 4 weeks apart.

The Recommended Immunization Schedules for Persons Aged 0–18 Years are approved by the Advisory Committee on Immunization Practices (www.cdc.gov/vaccines/recs/acip), the American Academy of Pediatrics (http://www.aap.org), and the American Academy of Family Physicians (http://www.aafp.org).

DEPARTMENT OF HEALTH AND HUMAN SERVICES • CENTERS FOR DISEASE CONTROL AND PREVENTION
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CS103164

Catch-up Immunization Schedule

UNITED STATES • 2008

for Persons Aged 4 Months–18 Years Who Start Late or Who Are More Than 1 Month Behind

The table below provides catch-up schedules and minimum intervals between doses for children whose vaccinations have been delayed. A vaccine series does not need to be restarted, regardless of the time that has elapsed between doses. Use the section appropriate for the child's age.

CATCH-UP SCHEDULE FOR PERSONS AGED 4 MONTHS–6 YEARS					
Vaccine	Minimum Age for Dose 1	Minimum Interval Between Doses			
		Dose 1 to Dose 2	Dose 2 to Dose 3	Dose 3 to Dose 4	Dose 4 to Dose 5
Hepatitis B[1]	Birth	4 weeks	8 weeks (and 16 weeks after first dose)		
Rotavirus[2]	6 wks	4 weeks	4 weeks		
Diphtheria, Tetanus, Pertussis[3]	6 wks	4 weeks	4 weeks	6 months	6 months[3]
Haemophilus influenzae type b[4]	6 wks	4 weeks if first dose administered at younger than 12 months of age 8 weeks (as final dose) if first dose administered at age 12-14 months No further doses needed if first dose administered at 15 months of age or older	4 weeks[4] if current age is younger than 12 months 8 weeks (as final dose)[4] if current age is 12 months or older and second dose administered at younger than 15 months of age No further doses needed if previous dose administered at age 15 months or older	8 weeks (as final dose) This dose only necessary for children aged 12 months–5 years who received 3 doses before age 12 months	
Pneumococcal[5]	6 wks	4 weeks if first dose administered at younger than 12 months of age 8 weeks (as final dose) if first dose administered at age 12 months or older or current age 24–59 months No further doses needed for healthy children if first dose administered at age 24 months or older	4 weeks if current age is younger than 12 months 8 weeks (as final dose) if current age is 12 months or older No further doses needed for healthy children if previous dose administered at age 24 months or older	8 weeks (as final dose) This dose only necessary for children aged 12 months–5 years who received 3 doses before age 12 months	
Inactivated Poliovirus[6]	6 wks	4 weeks	4 weeks	4 weeks[6]	
Measles, Mumps, Rubella[7]	12 mos	4 weeks			
Varicella[8]	12 mos	3 months			
Hepatitis A[9]	12 mos	6 months			
CATCH-UP SCHEDULE FOR PERSONS AGED 7–18 YEARS					
Tetanus, Diphtheria/ Tetanus, Diphtheria, Pertussis[10]	7 yrs[10]	4 weeks	4 weeks if first dose administered at younger than 12 months of age 6 months if first dose administered at age 12 months or older	6 months if first dose administered at younger than 12 months of age	
Human Papillomavirus[11]	9 yrs	4 weeks	12 weeks (and 24 weeks after the first dose)		
Hepatitis A[9]	12 mos	6 months			
Hepatitis B[1]	Birth	4 weeks	8 weeks (and 16 weeks after first dose)		
Inactivated Poliovirus[6]	6 wks	4 weeks	4 weeks	4 weeks[6]	
Measles, Mumps, Rubella[7]	12 mos	4 weeks			
Varicella[8]	12 mos	4 weeks if first dose administered at age 13 years or older 3 months if first dose administered at younger than 13 years of age			

1. Hepatitis B vaccine (HepB).
- Administer the 3-dose series to those who were not previously vaccinated.
- A 2-dose series of Recombivax HB® is licensed for children aged 11–15 years.

2. Rotavirus vaccine (Rota).
- Do not start the series later than age 12 weeks.
- Administer the final dose in the series by age 32 weeks.
- Do not administer a dose later than age 32 weeks.
- Data on safety and efficacy outside of these age ranges are insufficient.

3. Diphtheria and tetanus toxoids and acellular pertussis vaccine (DTaP).
- The fifth dose is not necessary if the fourth dose was administered at age 4 years or older.
- DTaP is not indicated for persons aged 7 years or older.

4. *Haemophilus influenzae* type b conjugate vaccine (Hib).
- Vaccine is not generally recommended for children aged 5 years or older.
- If current age is younger than 12 months and the first 2 doses were PRP-OMP (PedvaxHIB® or ComVax® [Merck]), the third (and final) dose should be administered at age 12–15 months and at least 8 weeks after the second dose.
- If first dose was administered at age 7–11 months, administer 2 doses separated by 4 weeks plus a booster at age 12–15 months.

5. Pneumococcal conjugate vaccine (PCV).
- Administer one dose of PCV to all healthy children aged 24–59 months having any incomplete schedule.
- For children with underlying medical conditions, administer 2 doses of PCV at least 8 weeks apart if previously received less than 3 doses, or 1 dose of PCV if previously received 3 doses.

6. Inactivated poliovirus vaccine (IPV).
- For children who received an all-IPV or all-oral poliovirus (OPV) series, a fourth dose is not necessary if third dose was administered at age 4 years or older.
- If both OPV and IPV were administered as part of a series, a total of 4 doses should be administered, regardless of the child's current age.
- IPV is not routinely recommended for persons aged 18 years and older.

7. Measles, mumps, and rubella vaccine (MMR).
- The second dose of MMR is recommended routinely at age 4–6 years but may be administered earlier if desired.
- If not previously vaccinated, administer 2 doses of MMR during any visit with 4 or more weeks between the doses.

8. Varicella vaccine.
- The second dose of varicella vaccine is recommended routinely at age 4–6 years but may be administered earlier if desired.
- Do not repeat the second dose in persons younger than 13 years of age if administered 28 or more days after the first dose.

9. Hepatitis A vaccine (HepA).
- HepA is recommended for certain groups of children, including in areas where vaccination programs target older children. See *MMWR* 2006;55(No. RR-7):1–23.

10. Tetanus and diphtheria toxoids vaccine (Td) and tetanus and diphtheria toxoids and acellular pertussis vaccine (Tdap).
- Tdap should be substituted for a single dose of Td in the primary catch-up series or as a booster if age appropriate; use Td for other doses.
- A 5-year interval from the last Td dose is encouraged when Tdap is used as a booster dose. A booster (fourth) dose is needed if any of the previous doses were administered at younger than 12 months of age. Refer to ACIP recommendations for further information. See *MMWR* 2006;55(No. RR-3).

11. Human papillomavirus vaccine (HPV).
- Administer the HPV vaccine series to females at age 13–18 years if not previously vaccinated.

Information about reporting reactions after immunization is available online at http://www.vaers.hhs.gov or by telephone via the 24-hour national toll-free information line 800-822-7967. Suspected cases of vaccine-preventable diseases should be reported to the state or local health department. Additional information, including precautions and contraindications for immunization, is available from the National Center for Immunization and Respiratory Diseases at http://www.cdc.gov/vaccines or telephone, 800-CDC-INFO (800-232-4636).

CS113997

CALIFORNIA STATE BOARD OF PHARMACY
1625 N Market Blvd., Suite N-219, Sacramento, CA 95834

Be Aware & Take Care: Talk to your pharmacist!

Why Vaccinate?

Vaccines are a safe, cost effective and efficient way to prevent sickness and death from infectious diseases.

One of the greatest public health achievements of the 20th century is the ability to prevent disability and death from infectious diseases for individuals, and to control the spread of infectious diseases for individuals.

Some diseases once considered practically eradicated have re-emerged in recent years, and new infectious agents and infectious diseases remain major causes of illness, disability and death.

Healthy People 2010 contains several objectives specific to immunizations, including increasing levels of immunizations and expanding immunization laws.

Diseases that could be prevented by vaccines kill thousands of American adults every year.

CALIFORNIA STATE BOARD OF PHARMACY

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Be Aware & Take Care: Talk to your pharmacist!

What Immunizations are Covered by the Schedules

The CDC currently has 10 immunizations recommended for persons aged 7-18 and adults.

Recommended Immunization Schedule for Persons Aged 7-18 Years	Recommended adult Immunization Schedule
Tetanus, Diphtheria, Pertussis	Tetanus, Diphtheria, Pertussis
Human Papillomavirus	Human Papillomavirus
Meningococcal	Meningococcal
Pneumococcal	Pneumococcal
Influenza	Influenza
Hepatitis A	Hepatitis A
Hepatitis B	Hepatitis B
Inactivated Poliovirus	Measles, Mumps, Rubella
Measles, Mumps, Rubella	Varicella
Varicella	Zoster

The majority of the estimated 60,000 new hepatitis B infections each year strike adolescents and young adults. The hepatitis B virus is 100 times more infectious than HIV.

The hepatitis B vaccine is recognized as the first anti-cancer vaccine because it can prevent primary liver cancer caused by hepatitis B infection.

Combined, influenza and pneumonia are the 8th leading cause of death in people of all ages and the 7th leading cause of death in people over the age of 65.

During most influenza seasons, 5% to 20% of the people in the United States may be infected with influenza virus. Influenza immunization can reduce physician visits, lost work days, and reduce antibiotic use.

Nearly one in every 10 people who get diphtheria will die from it.

About 1 out of every 20 people who get pneumococcal pneumonia die from it, as to about 2 people out of 10 who get bacteremia and 3 people out of 10 who get meningitis.

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Be Aware & Take Care: Talk to your pharmacist!

What Immunizations are Covered by the Schedules

About 2,600 people get meningococcal disease each year in the U.S. 10 – 15% of these people die, in spite of treatment with antibiotics, and of those who live, another 11-19% lose their arms or legs, become deaf, have problems with their nervous systems, become mentally retarded, or suffer seizure or strokes.

Tetanus leads to death in up to 2 cases out of 10.

Diptheria can lead to breathing problems, paralysis, heart failure and death.

Genital human papillomavirus (HPV) can cause cervical cancer in women. Every year in the U.S. about 10,000 women get cervical cancer and 3,700 die from it. More than 50% of sexually active men and women are infected with HPV at some time in their lives.

Hepatitis A can cause mild flu like symptoms, jaundice and sever stomach pains and diarrhea. Up to one in five persons with hepatitis A will have to be hospitalized.

Polio used to be very common in the United States. It used to paralyze and kill thousands of people a year before the vaccine.[6] This disease however is still common in other parts of the world. Given the mobility of our society, this creates a risk for a reemergence in the U.S. if we stop this vaccination.

Measles virus causes rash, cough, runny nose, eye irritation and fever and can lead to ear infection, pneumonia, seizures, brain damage and death.[6]

Mumps can lead to deafness, meningitis, painful swelling of the testicles or ovaries and rarely death.

Rubella virus causes rash, mild fever and arthritis.

Improved Access for Californians to Pharmacist Provided Immunization

Why Pharmacists?

Community Accessibility

- Pharmacists represent the third largest health professional group in the United States. Approximately 25,000 are licensed and actively practicing in California alone.
- There are an estimated 5,000 pharmacies in over 1,100 zip codes in California, making access to pharmaceutical services very convenient.
- Pharmacists are on the front line of preventive care.
- Appointments are often not necessary to see a pharmacist.

Professional Training

- All pharmacy graduates today receive a Doctor of Pharmacy (PharmD) after four years of pharmacy school beyond undergraduate work, and many pursue post-doctoral residencies. Pharmacists are trained, either in school or after graduation, to screen, administer, and to properly deal with any adverse events that may arise from vaccines.
- Pharmacists are drug and vaccine experts by virtue of their extensive training and practice. They are also proven patient counselors, able to translate complex medical language into something easily understood by patients.
- Pharmacists are consistently rated in the top 2 professions for honesty and integrity by the USC Today/Gallup Poll.

Current Situation

- California Business and Professions Code, Section 4052(9), authorizes a pharmacist to administer any immunization, but only under the protocol of a prescriber. By Board of Pharmacy interpretation, the provider does not have to be on site while vaccines are administered.
- Many pharmacists are unable to obtain a prescriber's signature on their vaccination protocol, making them unable to administer vaccines. Even after extensive education of physicians regarding the minimal liability incurred, many remain apprehensive and choose not to sign immunization protocols with pharmacists.
- Independent pharmacies are the hardest hit by the need for a prescriber protocol. These small businesses often serve low-income, ethnically diverse communities in suburban and rural locations throughout California.
- Access disparities must be amended in order for California to achieve full immunization coverage. However, due to current law, pharmacy-based immunization falls short of its potential to close the access gap.

This Bill

- This bill provides Californians with greater access to routine vaccinations by allowing a pharmacist to administer CDC recommended routine immunizations to patients 7 years of age and older, pursuant to ACIP recommendations.
- This bill provides that pharmacists can administer immunizations by either following the CDC recommended routine immunization guidelines, or by following a prescriber-authorized protocol.
- This bill mandates standardized training, reporting, and continuing education for pharmacists who administer immunizations in California.

Attachment B-5

Elements of a Prescription Label

Proposal to Amend Business and Professions Code section 4076
Fact Sheet

§4076 – Prescription Container – Requirements for Labeling

(a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

(1) Except where the prescriber or the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052 orders otherwise, either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used. Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.

(2) The directions for the use of the drug.

(3) The name of the patient or patients.

(4) The name of the prescriber or, if applicable, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052.

(5) The date of issue.

(6) The name and address of the pharmacy, and prescription number or other means of identifying the prescription.

(7) The strength of the drug or drugs dispensed.

(8) The quantity of the drug or drugs dispensed.

(9) The expiration date of the effectiveness of the drug dispensed.

(10) The ~~condition~~ purpose for which the drug was prescribed if requested by the patient ~~and the condition is indicated on the prescription~~.

(11) (A) ~~Commencing January 1, 2006, t~~The physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules, except as follows:

(i) Prescriptions dispensed by a veterinarian.

(ii) An exemption from the requirements of this paragraph shall be granted to a new drug for the first 120 days that the drug is on the market and for the 90 days during which the national reference file has no description on file.

(iii) Dispensed medications for which no physical description exists in any commercially available database.

(B) This paragraph applies to outpatient pharmacies only.

(c) A pharmacist initiating and administering any immunization pursuant to this section shall also complete 3 hours of immunization-related continuing education coursework annually. Failure at any time to meet this requirement shall, in addition to any other sanctions, require the pharmacist to re-take the training identified in subdivision (b) prior to administration of any further immunization(s).

(d) A pharmacist shall at all times maintain current Basic Life Support certification.

(e) At the time of administration of an immunization, the pharmacist shall:

(1) Provide the patient or patient's agent with the appropriate Vaccine Information Statement for each immunization administered; and

(2) Provide documentation of administration of the immunization to the patient and patient's physician or primary care provider, if one can be identified.

(f) Any pharmacist initiating and administering vaccines pursuant to this section may initiate and administer epinephrine by injection for severe allergic reactions.

(g) Any adverse event shall be reported to the Vaccine Adverse Event Reporting System within the U.S. Department of Health and Human Services.

(h) The pharmacist shall maintain an immunization administration record, which includes, but is not limited to, the name of the vaccine, expiration date, date of administration, manufacturer and lot number, administration site and route, Vaccine Information Statement date, and the name and title of the person administering, for the longer of the following periods:

(1) Ten years from the date of administration; or

(2) If less than 18 years at the time of administration, three years beyond the patient's eighteenth birthday.

(i) Upon receipt of a vaccine as authorized by this section, a pharmacist is responsible to assure that proper vaccine temperatures are maintained during subsequent storage and handling to preserve potency.

California State Board of Pharmacy
Business and Professions Code Section 4076, Prescription Labels

Summary

Business and Professions Code section 4001.1 states that protection of the public is the board's highest priority. Further, Business and Professions Code section 4076 defines in general the labeling requirements for prescription labels, including the requirement that the label include the condition for which the drug was prescribed if requested by the patient and indicated on the prescription.

In 2007, as a result of SB 472 (Corbett, Statutes of 2007), the board was charged with standardizing the prescription label to make it patient-centered. As part of this mandate, the board is required to seek information from specified groups and to consider this information in the development of these requirements. The board has held public meetings, attended community events and consumer surveys designed to elicit information from consumers. To date the board has received over 394 responses to our survey with 99 respondents either indicating the purpose of the medication as one of the most important elements of the label or suggesting that it should be included on the label.

The board's legislative proposal for 2009 is to change the requirements of prescription label to include the purpose of the medicine if requested by the patient, rather than the condition for which it is prescribed if requested by the patient and included by the prescriber.

The change is supported by:

- The California Pharmacy Foundation;
- Research that demonstrates that patients do not fully understand how and why they are taking their medicine; and
- Recommendations by the SCR 49 Panel.

Legislative History

Over the last several years, similar legislative proposals have failed to pass. Below is a brief summary of each.

AB 1276 (Karnette, 2007) – This proposal would have required prescribers of medication to ask a patient if they wanted the intended use on the prescription label. (Failed passage in committee.)

AB 657 – (Karnette, 2005) – This proposal would have altered the prescription labeling requirement and would have required the prescription label to include the intended purpose of the drugs. (Hearing cancelled by author.)

AB 288 – (Mountjoy, 2005) – This proposal would have amended the prescription labeling requirement to include the condition for which the drug is prescribed unless the patient, physician or legal guardian requested that the information be omitted. (Hearing cancelled by author.)

AB 2125 – (Levine, 2004) – This proposal would have required a physician and surgeon to indicate the patient's diagnosis on each prescription written, unless directed otherwise by the patient. In addition, this proposal would have amended the prescription labeling requirement to require that the condition be included on the label unless otherwise directed by the patient. (Hearing cancelled by author.)

This proposal

Would replace the condition for which a medicine is prescribed and replace it with the medicine's purpose. Such a change may reduce medication errors, particularly for patients who take multiple medications, is consistent with the findings of the SCR 49 panel and is consistent with the board's survey.

Legislative Proposal Regarding Return of Medicine to Reverse Distributors
Proposal to Amend Business & Professions Code
Sections 4040.5, 4043 and 4081

4040.5. "Reverse distributor" means every person who acts as an agent for pharmacies, drug wholesalers, manufacturers, and other entities by receiving, inventorying, and managing the disposition of outdated or nonsalable dangerous drugs. Reverse distributors shall not accept the return of dangerous drugs that have been dispensed to patients that are later returned to the pharmacy or another licensed entity. Instead, dangerous drugs returned by a patient to a pharmacy, if accepted by the pharmacy, shall only be picked up or handled (if mailed) by a licensed integrated waste hauler.

For purposes of this section, "dispensed" means that the dangerous drugs have been provided to the patient or patient's agent, and taken from the pharmacy.

4043. (a) "Wholesaler" means and includes a person who acts as a wholesale merchant, broker, jobber, customs broker, reverse distributor, agent, or a nonresident wholesaler, who sells for resale, or negotiates for distribution, or takes possession of, any drug or device included in Section 4022. Unless otherwise authorized by law, a wholesaler may not
store, warehouse, or authorize the storage or warehousing of drugs with any person or at any location not licensed by the board.
~~(b) This section shall become operative January 1, 2006.~~

4081. (a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

(b) Records of all drugs returned to a wholesaler or provided to a reverse distributor shall document the quantity of drugs returned, the date and the entity to which the drugs were provided. Records of all drugs returned to a licensed integrated waste hauler shall list the volume in weight or measurement of the pharmaceutical waste, the date and name of the licensed waste hauler.

(c) The owner, officer, and partner of a pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or representative-in-charge, for maintaining the records and inventory described in this section.

(~~c~~ d) The pharmacist-in-charge or representative-in-charge shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge or representative-in-charge had no knowledge, or in which he or she did not knowingly participate.

~~(d) This section shall become operative on January 1, 2006.~~

2009-10 Legislative Session
Legislation Introduced Impacting this Practice of Pharmacy
Or the Board's Jurisdiction

SB 26 (Simitian) Home Generated Pharmaceutical Waste

BILL NUMBER: SB 26 INTRODUCED
BILL TEXT

INTRODUCED BY Senator Simitian

DECEMBER 1, 2008

An act to add Sections 4001.2, 4068.1, and 4146 to the Business and Professions Code, to amend Sections 117700, 117935, 117945, 117960, 118000, 118040, 118147, and 118165 of, and to add Sections 117642, 117669, 117748, 117904.5, 118031, and 118041 to, the Health and Safety Code, and to amend Section 47200 of the Public Resources Code, relating to pharmaceutical waste.

LEGISLATIVE COUNSEL'S DIGEST

SB 26, as introduced, Simitian. Home-generated pharmaceutical waste.

The existing Pharmacy Law establishes the California State Board of Pharmacy, prescribes the licensing, regulatory, and disciplinary functions of the board, and authorizes the board to adopt rules and regulations necessary to administer laws governing the operation of pharmacies and the dispensing of drugs and devices to the public.

This bill would require the board to coordinate with other state agencies, local governments, drug manufacturers, and pharmacies to develop sustainable, efficient policies and programs to manage pharmaceutical wastes and the disposal of devices. The bill would authorize a pharmacy to accept the return of home-generated pharmaceutical waste and home-generated sharps waste, as defined.

Existing law, the California Integrated Waste Management Act of 1989, requires the California Integrated Waste Management Board to adopt regulations that set forth minimum standards for solid waste management and require assurance of financial ability to pay for specified injury and property damage claims resulting from the operation of a disposal facility. The act requires the board to expend moneys from the Solid Waste Management Account in the Integrated Waste Management Fund, upon appropriation by the Legislature, for the making of grants to cities, counties, or other

local agencies with responsibility for solid waste management, and for local programs to help prevent the disposal of hazardous wastes at disposal sites, as provided.

This bill would require that local programs to help prevent the disposal of home-generated sharps waste and home-generated pharmaceutical waste at disposal sites also be included among the types of local programs that may be funded by such a grant.

Existing law, the Medical Waste Management Act, requires the State Department of Public Health to regulate the management and handling of medical waste, as defined. Under existing law, certain items, such as household waste, are specifically excluded from the definition of medical waste.

This bill would also exclude home-generated pharmaceutical waste, as defined, from the definition of medical waste.

Existing law regulates the methods of consolidating, storing, and transporting medical waste and home-generated sharps waste. Violation of these provisions is a crime.

This bill would regulate consolidation points for home-generated pharmaceutical waste, as defined, as well as transportation and disposal of that waste by both hazardous waste haulers and common carriers, as defined. By expanding the definition of a crime, this bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 4001.2 is added to the Business and Professions Code, to read:

4001.2. To further the purposes of Section 4001.1, and to protect the public from hazards caused by the improper management and disposal of waste drugs and devices, the California State Board of Pharmacy shall coordinate with other state agencies, local governments, drug manufacturers, and pharmacies to develop sustainable, efficient policies and programs to properly manage pharmaceutical wastes and the disposal of these wastes.

SEC. 2. Section 4068.1 is added to the Business and Professions Code, to read:

4068.1. A pharmacy may accept the return of home-generated pharmaceutical waste, as defined in Section 117769 of the Health and Safety Code, from the public.

SEC. 3. Section 4146 is added to the Business and Professions Code, to read:

4146. A pharmacy may accept the return of home-generated sharps waste, as defined in Section 117671 of the Health and Safety Code, from a person if the waste is contained in a sharps container.

SEC. 4. Section 117642 is added to the Health and Safety Code, to read:

117642. "Common carrier" means a person or company that hauls for hire goods, including, but not limited to, pharmaceutical waste or home-generated pharmaceutical waste. Home-generated pharmaceutical waste must have been consolidated at a location approved by the enforcement agency as a home-generated pharmaceutical waste consolidation point.

SEC. 5. Section 117669 is added to the Health and Safety Code, to read:

117669. "Home-generated pharmaceutical waste" means prescribed and over-the-counter drugs derived from a household.

SEC. 6. Section 117700 of the Health and Safety Code is amended to read:

117700. Medical waste does not include any of the following:

(a) Waste generated in food processing or biotechnology that does not contain an infectious agent as defined in Section 117675.

(b) Waste generated in biotechnology that does not contain human blood or blood products or animal blood or blood products suspected of being contaminated with infectious agents known to be communicable to humans.

(c) Urine, feces, saliva, sputum, nasal secretions, sweat, tears, or vomitus, unless it contains fluid blood, as provided in subdivision (d) of Section 117635.

(d) Waste ~~which~~ *that* is not biohazardous, such as paper towels, paper products, articles containing nonfluid blood, and other medical solid waste products commonly found in the facilities of medical waste generators.

(e) Hazardous waste, radioactive waste, or household waste, including, but not limited to, home-generated sharps waste, as defined in Section 117671 *, and home-generated pharmaceut ical waste, as defined in Section 117669* .

(f) Waste generated from normal and legal veterinarian, agricultural, and animal livestock management practices on a farm or ranch.

SEC. 7. Section 117748 is added to the Health and Safety Code, to read:

117748. "Pharmaceutical waste" means any pharmaceutical, prescription, or over-the-counter human or veterinary drug, including, but not limited to, a drug, as defined in Section 109925, or the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 321(g)(1)) that meets any of the following requirements:

(a) The drug may no longer be sold or dispensed because it has expired.

(b) The drug can no longer be used for its intended purpose.

(c) The drug has been discarded.

(d) The drug has been consolidated at a location approved by the enforcement agency as a home-generated pharmaceutical waste consolidation point.

SEC. 8. Section 117904.5 is added to the Health and Safety Code, to read:

117904.5. (a) In addition to the consolidation points authorized pursuant to Section 118147, the enforcement agency may approve a

location as a point of consolidation for the collection of home-generated pharmaceutical waste. These locations may include, but are not limited to, pharmacies, heath care facilities, veterinarian offices, clinics, household hazardous waste programs, solid waste facilities, senior centers, or government offices.

(b) A consolidation location approved pursuant to this section shall be known as a home-generated pharmaceutical waste consolidation point.

(c) A home-generated pharmaceutical waste consolidation point is not subject to the requirements of Chapter 9 (commencing with Section 118275) of Part 14 of Division 4, to the permit requirements of this part, or to any permit or registration fees, with regard to the activity of consolidating home-generated pharmaceutical waste pursuant to this section.

(d) A home-generated pharmaceutical waste consolidation point shall comply with all of the following requirements:

(1) It shall be approved by the enforcement agency for this purpose.

(2) The home-generated pharmaceutical waste collected and consolidated at the facility shall be collected and contained in a leak-resistant container and placed in a secure area that does not allow the waste to be accessed or salvaged by unauthorized persons.

(3) Containers ready for disposal shall not be held for more than 90 days without the written approval of the enforcement agency.

(e) An operator of a home-generated pharmaceutical waste consolidation point that is approved pursuant to this section shall not be considered a generator of that waste.

(f) The end disposal facility that treats the home-generated pharmaceutical waste shall maintain the tracking documents required by Section 118040 or 118041, as applicable, and Section 118165 with regard to the pharmaceutical waste.

(g) Nothing in this section shall exempt any person from any federal or state law governing pharmaceuticals.

SEC. 9. Section 117935 of the Health and Safety Code is amended to read:

117935. Any small quantity generator required to register with the enforcement agency pursuant to Section 117930 shall file with the enforcement agency a medical waste management plan, on forms prescribed by the enforcement agency containing, but not limited to, all of the following:

(a) The name of the person.

(b) The business address of the person.

(c) The type of business.

(d) The types, and the estimated average monthly quantity, of medical waste generated.

(e) The type of treatment used onsite.

(f) The name and business address of the registered hazardous waste hauler used by the generator for backup treatment and disposal, for waste when the onsite treatment method is not appropriate due to the hazardous or radioactive characteristics of the waste, ~~or~~ the name of the registered hazardous waste hauler used by the generator to have untreated medical waste removed for treatment and disposal *, and, if applicable, the name of the*

common carrier used by the generator to transport pharmaceutical waste offsite for treatment and disposal .

(g) A statement indicating that the generator is hauling the medical waste generated in his or her business pursuant to Section 118030 and the name and any business address of the treatment and disposal facilities to which the waste is being hauled, if applicable.

(h) The name and business address of the registered hazardous waste hauler service provided by the building management to which the building tenants may subscribe or are required by the building management to subscribe and the name and business address of the treatment and disposal facilities used, if applicable.

(i) A statement certifying that the information provided is complete and accurate.

SEC. 10. Section 117945 of the Health and Safety Code is amended to read:

117945. Small quantity generators who are not required to register pursuant to this chapter shall maintain on file in their office all of following:

(a) An information document stating how the generator contains, stores, treats, and disposes of any medical waste generated through any act or process of the generator.

(b) Records of any medical waste transported offsite for treatment and disposal, including the quantity of waste transported, the date transported, and the name of the registered hazardous waste hauler or individual hauling the waste pursuant to Section 118030 *, or the name of the common carrier hauling pharmaceutical waste pursuant to Section 118031* . The small quantity generator shall maintain these records for not less than two years.

SEC. 11. Section 117960 of the Health and Safety Code is amended to read:

117960. Any large quantity generator required to register with the enforcement agency pursuant to Section 117950 shall file with the enforcement agency a medical waste management plan, on forms prescribed by the enforcement agency containing, but not limited to, all of the following:

(a) The name of the person.

(b) The business address of the person.

(c) The type of business.

(d) The types, and the estimated average monthly quantity, of medical waste generated.

(e) The type of treatment used onsite, if applicable. For generators with onsite medical waste treatment facilities, including incinerators or steam sterilizers or other treatment facilities as determined by the enforcement agency, the treatment capacity of the onsite treatment facility.

(f) The name and business address of the registered hazardous waste hauler used by the generator to have untreated medical waste removed for treatment, if applicable *, or the name of the common carrier hauling pharmaceutical waste pursuant to Section 118031*

.

(g) The name and business address of the registered hazardous waste hauler service provided by the building management to which the

building tenants may subscribe or are required by the building management to subscribe, if applicable.

(h) The name and business address of the offsite medical waste treatment facility to which the medical waste is being hauled, if applicable.

(i) An emergency action plan complying with regulations adopted by the department.

(j) A statement certifying that the information provided is complete and accurate.

SEC. 12. Section 118000 of the Health and Safety Code is amended to read:

118000. (a) Except as otherwise exempted pursuant to Section 118030 *or 118031* , all medical waste transported to an offsite medical waste treatment facility shall be transported in accordance with this chapter by a registered hazardous waste transporter issued a registration certificate pursuant to Chapter 6 (commencing with Section 118025) and Article 6.5 (commencing with Section 25167.1) of Chapter 6.5 of Division 20. A hazardous waste transporter transporting medical waste shall have a copy of the transporter's valid hazardous waste transporter registration certificate in the transporter's possession while transporting medical waste. The transporter shall show the certificate, upon demand, to any enforcement agency personnel or authorized employee of the Department of the California Highway Patrol.

(b) Except for small quantity generators transporting medical waste pursuant to Section 118030 *or small quantity generators or common carriers transporting home-generated pharmaceutical waste pursuant to Section 118031* , medical waste shall be transported to a permitted offsite medical waste treatment facility or a permitted transfer station in leak-resistant and fully enclosed rigid secondary containers that are then loaded into an enclosed cargo body.

(c) A person shall not transport medical waste in the same vehicle with other waste unless the medical waste is separately contained in rigid containers or kept separate by barriers from other waste, or unless all of the waste is to be handled as medical waste in accordance with this part.

(d) Medical waste shall only be transported to a permitted medical waste treatment facility, or to a transfer station or another registered generator for the purpose of consolidation before treatment and disposal, pursuant to this part.

(e) Facilities for the transfer of medical waste shall be annually inspected and issued permits in accordance with the regulations adopted pursuant to this part.

(f) Any persons manually loading or unloading containers of medical waste shall be provided by their employer at the beginning of each shift with, and shall be required to wear, clean and protective gloves and coveralls, changeable lab coats, or other protective clothing. The department may require, by regulation, other protective devices appropriate to the type of medical waste being handled.

SEC. 13. Section 118031 is added to the Health and Safety Code, to read:

118031. Pharmaceutical waste may be shipped by a common carrier

if the generator or home-generated pharmaceutical waste consolidation point meets the following requirements:

(a) The facility shall maintain documentation as required in Sections 118040 and 118041.

(b) The waste products are transported to any of the following:

(1) A medical waste facility.

(2) A hazardous waste facility.

(3) A reverse distributor, with the final destination of a medical or hazardous waste facility.

SEC. 14. Section 118040 of the Health and Safety Code is amended to read:

118040. (a) Except with regard to sharps waste consolidated by a home-generated sharps consolidation point approved pursuant to Section 117904, *pharmaceutical waste or home-generated pharmaceutical waste consolidated by a home-generated pharmaceu tical waste consolidation point approved pursuant to Section 117904.5, or home-generated pharmaceutical waste transported pursuant to Section 118031,* a hazardous waste transporter or generator transporting medical waste shall maintain a completed tracking document of all medical waste removed for treatment or disposal. A hazardous waste transporter or generator who transports medical waste to a facility, other than the final medical waste treatment facility, shall also maintain tracking documents which show the name, address, and telephone number of the medical waste generator, for purposes of tracking the generator of medical waste when the waste is transported to the final medical waste treatment facility. At the time that the medical waste is received by a hazardous waste transporter, the transporter shall provide the medical waste generator with a copy of the tracking document for the generator's medical waste records. The transporter or generator transporting medical waste shall maintain its copy of the tracking document for three years.

(b) The tracking document shall include, but not be limited to, all of the following information:

(1) The name, address, telephone number, and registration number of the transporter, unless transported pursuant to Section 118030.

(2) The type and quantity of medical waste transported.

(3) The name, address, and telephone number of the generator.

(4) The name, address, telephone number, permit number, and the signature of an authorized representative of the permitted facility receiving the medical waste.

(5) The date that the medical waste is collected or removed from the generator's facility, the date that the medical waste is received by the transfer station, the registered large quantity generator, or point of consolidation, if applicable, and the date that the medical waste is received by the treatment facility.

(c) Any hazardous waste transporter or generator transporting medical waste in a vehicle shall have a tracking document in his or her possession while transporting the medical waste. The tracking document shall be shown upon demand to any enforcement agency personnel or officer of the Department of the California Highway Patrol. If the medical waste is transported by rail, vessel, or air, the railroad corporation, vessel operator, or airline shall enter on

the shipping papers any information concerning the medical waste that the enforcement agency may require.

(d) A hazardous waste transporter or a generator transporting medical waste shall provide the facility receiving the medical waste with the original tracking document.

(e) Each hazardous waste transporter and each medical waste treatment facility shall provide tracking data periodically and in a format as determined by the department.

(f) Medical waste transported out of state shall be consigned to a permitted medical waste treatment facility in the receiving state. If there is no permitted medical waste treatment facility in the receiving state or if the medical waste is crossing an international border, the medical waste shall be treated in accordance with Chapter 8 (commencing with Section 118215) prior to being transported out of the state.

SEC. 15. Section 118041 is added to the Health and Safety Code, to read:

118041. (a) A person transporting pharmaceutical waste shall maintain a completed tracking document of all pharmaceutical waste removed for treatment or disposal. A copy of the tracking document shall be included with the container holding the pharmaceutical waste.

(b) The tracking document shall include, but not be limited to, all of the following information:

(1) The name, address, and telephone number of the generator.

(2) Specific information indicating that pharmaceutical waste is being transported.

(3) The name, address, and telephone number of the person transporting the waste.

(4) The name, address, telephone number, and permit number of the permitted treatment facility or transfer station to which the pharmaceutical waste is being sent.

(5) The date that the pharmaceutical waste was collected or removed from the generator or home-generated pharmaceutical waste consolidation point.

(c) A person tracking pharmaceutical waste shall have a tracking document for the waste in his or her possession while transporting the waste. The tracking document shall be shown, upon demand, to any enforcement agency personnel or officer of the Department of the California Highway Patrol.

(d) A medical waste treatment facility and transfer station shall date and sign a copy of the tracking document upon receipt, periodically provide data in a format determined by the department, and shall maintain a copy of the tracking document for three years.

(e) This section does not prohibit the use of a single document to verify the return of more than one container to a parent organization or another health care facility for the purpose of consolidation before treatment and disposal of the pharmaceutical waste over a period of time, if the form or log is maintained in the files of the parent organization or other health care facility that receives the waste.

(f) Pharmaceutical waste transported out of state shall be consigned to a permitted medical waste treatment facility in the

receiving state. If there is no permitted medical waste treatment facility in the receiving state, or if the waste is crossing an international border, the home-generated pharmaceutical waste shall be treated pursuant to Section 118222 prior to being transported out of state.

SEC. 16. Section 118147 of the Health and Safety Code is amended to read:

118147. Notwithstanding any other provision of this chapter, a registered medical waste generator, which is a facility specified in subdivisions (a) and (b) of Section 117705, may accept home-generated sharps waste *and home-generated pharmaceutical waste* , to be consolidated with the facility's medical waste stream, subject to all of the following conditions:

(a) The generator of the *home-generated* sharps waste *or home-generated pharmaceutical waste* , a member of the generator's family, or a person authorized by the enforcement agency transports the sharps waste *or pharmaceutical waste* to the medical waste generator's facility.

(b) The *home-generated* sharps waste *or home-generated pharmaceutical waste* is accepted at a central location at the medical waste generator's facility.

(c) A reference to, and a description of, the actions taken pursuant to this section are included in the facility's medical waste management plan adopted pursuant to Section 117960.

SEC. 17. Section 118165 of the Health and Safety Code is amended to read:

118165. On and after April 1, 1991, all persons operating a medical waste treatment facility shall maintain individual records for a period of three years and shall report or submit to the enforcement agency upon request, all of the following information:

(a) The type of treatment facility and its capacity.

(b) All treatment facility operating records.

(c) Copies of the tracking documents for all medical waste it receives for treatment from offsite generators or from hazardous waste haulers *or common carriers, pursuant to Section 118041*

.

SEC. 18. Section 47200 of the Public Resources Code is amended to read:

47200. (a) The board shall expend funds from the account, upon appropriation by the Legislature, for the making of grants to cities, counties, or other local agencies with responsibility for solid waste management, and for local programs to help prevent the disposal of *home-generated sharps waste, as defined in Section 117671 of the Health and Safety Code, home-generated pharmaceutical waste, as defined in Section 117669 of the Health and Safety Code, and* hazardous wastes at disposal sites, including, but not limited to, programs to expand or initially implement household hazardous waste programs. In making grants pursuant to this section, the board shall give priority to funding programs that provide for the following:

(1) New programs for rural areas, underserved areas, and for small cities.

(2) Expansion of existing programs to provide for the collection of additional waste types, innovative or more cost-effective

collection methods, or expanded public education services.

(3) Regional household hazardous waste programs.

(b) (1) The total amount of grants made by the board pursuant to this section shall not exceed, in any one fiscal year, three million dollars ($3,000,000).

(2) Notwithstanding paragraph (1), the total amount of grants made by the board pursuant to this section may exceed three million dollars ($3,000,000) but shall not exceed six million dollars ($6,000,000), in any one fiscal year, if sufficient funds are appropriated from the Integrated Waste Management Account for this purpose.

SEC. 19. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

Bill No.:	**SB 26 (Simitian)**
Version:	**Introduced 12/1/08**
Date of Analysis:	**January 2, 2008**
Topic:	**Disposal of Pharmaceutical Wastes**

Analysis:

Board of Pharmacy

Pursuant to existing Pharmacy Law, the Board of Pharmacy oversees licensing, regulatory and disciplinary functions of the Board, and authorizes the Board to adopt rules and regulations necessary to administer laws governing the operation of pharmacies and the dispensing of drugs and devices to the public.

This Bill:

Requires the Board of Pharmacy to coordinate with other state agencies, local governments, etc., to develop sustainable, efficient policies and programs to manage pharmaceutical wastes and the disposal of devices. To that end, SB 26

- **Adds** section 4001.2 to the Business and Professions Code, requiring the Board to coordinate with other state agencies, etc., to develop sustainable efficient policies and programs to properly manage pharmaceutical wastes and the disposal of these wastes.

- **Adds** section 4068.1 to the B&P Code authorizing a pharmacy to accept the return of home-generated pharmaceutical waste, as defined.

- **Adds** section 4146 to the B&P Code providing that a pharmacy may accept the return of home-generated sharps waste, as defined.

(continued)

Integrated Waste Management Board / Department of Public Health

Existing law provides that through the Integrated Waste Management Act of 1989, the Integrated Waste Management Board oversees, among other things, regulations that that set forth standards for solid waste management, including the collection and transportation of wastes. This bill also amends provisions which regulate the management and handling of medical waste, as defined, which fall under the authority of the California Department of Public Health.

This bill:

- Defines "common carrier" (adds section 117642 to the H&S Code)
- Defines "home-generated pharmaceutical waste (adds section 117669 to the H&S Code)
- Defines "pharmaceutical waste" (adds section 117748 to the H&S Code).
- Amends various Health and Safety code sections regarding medical waste management plans, collection, record keeping, hauling, transportation and destruction of specified wastes (H&S sections 117935.5, 117945, 117960, 118000, 118031, 118040, 118041, 118147, and 118165).
- Excludes home-generated pharmaceutical waste from the definition of "medical waste" (amends H&S Code section 11700(e)).
- Adds section 117904.5 to the H&S Code regarding the approval of a location as a point of consolidation for the collection of home-generated pharmaceutical waste. These points may include, but are not limited to: **pharmacies**, health care facilities, veterinarian offices, clinics, household hazardous waste programs, solid waste facilities, senior centers, or government offices. This section provides that consolidation locations approved pursuant to this section shall be known as home-generated pharmaceutical waste consolidation points, and specifies that they are not subject to the permit requirements, or to any permit or registration fees. This section also specifies containers to be used for waste and other provisions related to the definition of generators of waste and requirements for tracking documents, as required.

FISCAL IMPACT

Unknown at this time.

COMMENTS:

Board staff will continue to work with the legal office to identify issues and seek clarification on the bill's impact to pharmacy law.

SUPPORT and OPPOSITION:

None known as of this date.

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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
LEGISLATION AND REGULATION COMMITTEE
MINUTES

DATE: January 7, 2009

LOCATION: Los Angeles International Airport
Samuel Greenberg Board Meeting Room
1 World Way
Los Angeles, CA 90045

BOARD MEMBERS PRESENT: Robert Graul, RPh, Chairperson
Andrea Zinder, Public Member, Chairperson
Robert Swart, PharmD

STAFF PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Tessa Fraga, Administrative Analyst
Tina Thomas, Enforcement Analyst

Chairperson Graul called the meeting to order at 1:07 p.m.

Regulation Report

1. Board Approved Regulation – Undergoing Administrative Review

Amend Section 1760 – Disciplinary Guidelines

Chairperson Graul provided a brief status update on the pending regulation change. At the April 2008 board meeting, the board voted to adopt a regulation change to amend Title 16 CCR 1760 – Disciplinary Guidelines. After receiving additional clarifying comments from counsel, board staff submitted the completed rulemaking to the Department for review and approval in September 2008. While the department did approve this regulation, State and Consumer Services Agency is concerned about the optional language relating to automatic revocation when a probationer fails to submit

cost recovery as mandated. As a result it is being brought back to the board for further consideration.

Executive Officer Herold provided a staff recommendation that the committee consider removing the one "optional term" to allow the board to continue to pursue the remaining changes of the Disciplinary Guidelines.

MOTION: Support to move forward with a 15-day notice as recommended,

M/S: RS/AZ

SUPPORT: 3 OPPOSE: 0 ABSTAIN: 0

2. Board Approved Regulations – Previously Noticed (Not for discussion at this meeting)

Chairperson Graul indicated that these items are not for discussion for the committee.

Chairperson Graul briefly discussed the two changes by title only.

a. Proposed Repeal of 16 CCR §§ 1716.1 and 1716.2 and Amendment to 16 CCR § 1751-1751.8 and Adoption of 16 CCR §§1735-1735.8

Currently, pharmacy law provides the authority for a pharmacist to compound drug products as well as compound sterile injectable products. As required in Business and Professions Code section 4127, the board adopted regulations to implement the provisions for pharmacies that compound sterile injectable products. There are no similar provisions in regulation to detail the requirements for pharmacies that complete general compounding. This proposal would establish guidelines to provide uniformity in compounding for California consumers.

The 45-day comment period began in September 2008 and a regulation hearing was held at the October 2008 Board Meeting. At the conclusion of the regulation hearing, the board voted to create a subcommittee of two board members to work with staff and fully consider all comments received both orally and in writing. The subcommittee will be providing recommendations for consideration and action by the board at the January 2009 Board Meeting.

b. Proposed Amendment to 16 CCR §1773 and Adoption of 16 CCR §1773.5 – Ethics Course.

In April 2007, the board established a subcommittee to examine the development of an ethics course for pharmacists as an enforcement option as part of discipline. Based on their discussion and work, the subcommittee recommended to the board that it vote to create a program similar to the program used by the Medical Board. This proposal

would establish in regulation the minimum requirements for the ethics program. These minimum requirements are designed to better guide the board and licensees when they are finding a course and will ensure that the course will be of high quality. This proposal will provide licensees with the necessary information to assist in their rehabilitation.

The board determined the requirements as necessary, based on testimony received during the October 2007 Board Meeting. During the meeting, the board received testimony from the Institute for Medical Quality (IMQ), the course provider for the Medical Board's ethics course. The board determined that a minimum of 14 direct contact hours is appropriate to allow for case presentations, group discussion and experiential exercises and role-playing to ensure sufficient time to discuss and evaluate situations. In addition, based on the recommendation of IMQ, the board's proposal also incorporates an additional eight hours of time to allow the pharmacist to complete self-reflection on the decisions made that led to the violations and ultimate referral to the program and post-classroom instruction for up to one year. This self-reflection includes completing questions as part of a background assessment. The two post-course longitudinal studies ensure that the pharmacist has successfully internalized the necessary changes to prevent future violations resulting from unethical behavior.

During the October 2008 board meeting, the board held a regulation hearing on the proposed changes. At the conclusion, the board directed staff to take all steps necessary to complete the rulemaking process, including preparing modified text for an additional 15-day comment period, which includes the following amendments: change the word "medicine" to "pharmacy" at proposed §1773.5(a)(5)(B). If after the 15-day public comment period, no adverse comments are received, the board authorized the Executive Officer to make any non-substantive changes to the proposed regulations before completing the rulemaking process, and adopt amendments to §1773 as filed and adopt §1773.5 of the proposed regulations with this modified text.

The 15-day comment period is over and no additional comments were received. Board staff will begin compiling the rulemaking and will submit it to the department during the first quarter of 2009.

3. Board Approved Regulations – Awaiting Notice

Chairperson Graul provided an update on board approved regulations that are awaiting notice.

a. Proposed Amendment to 16 CCR §1715 and 16 CCR §1784 - Section 100 Changes to Update the Self Assessment Forms for Pharmacies and Wholesalers

Section 1715 establishes requirements for the pharmacist-in-charge (PIC) of a licensed pharmacy to complete a self-assessment form to ensure compliance with pharmacy law. Section 1784 establishes the requirement for the designated representative-in-charge of a licensed wholesaler to complete a self-assessment form to ensure

compliance with pharmacy law. These self-assessment forms are designed to assist pharmacies and wholesalers in increasing their compliance with legal requirements and therefore increase public safety as a result of this compliance. Additionally, the forms make the pharmacy inspection process more meaningful and educational and provide relevant information to pharmacies and their PIC.

Chairperson Graul noted that staff will compile the section 100 regulation change package in the first quarter of 2009.

b. Proposed Addition to 16 CCR §1785 – Self-Assessment of a Veterinary Food-Animal Drug Retailer

The adoption of Section 1785 of the California Code of Regulations would establish a self-assessment form for veterinary food-animal drug retailers and require the designated representative-in-charge to complete this form to ensure compliance with pharmacy law. This form would also aid these licensees in complying with legal requirements of their operations and therefore increase public safety as a result.

The draft form was reviewed and approved at the September 2007 Enforcement Committee Meeting. During the October 2007 Board Meeting, the board voted to approve the regulation for the 45-day comment period.

Chairperson Graul advised that a copy of the draft language and form is provided, however board staff do not anticipate proceeding with this regulation change until the Licensing Committee completes its review of the Veterinary Food-Animal Drug Program for possible changes.

c. Proposed Adoption of 16 CCR §1751.8 – Accreditation Agencies for Pharmacies that Compound Injectable Sterile Drug Products

Business and Professions Code section 4127.1 requires a separate license to compound injectable sterile drug products. Section 4127.1(d) provides exemptions to the licensing requirement for pharmacies that have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation agencies approved by the board. Since the inception of this statute, the board has approved two such agencies.

This proposed regulation would specify the criteria the board uses to evaluate these agencies and was approved at the July 2007 Board Meeting. The board voted to move this proposal.

Chairperson Graul advised that a copy of the language as approved by the board was provided in the meeting materials.

d. Proposed Amendment to 16 CCR §§1721 and 1723.1 – Dishonest Conduct on a Pharmacist Licensure Examination/Confidentiality.

At the October 2007 Board Meeting, the board voted to approve proposed amendments to 16 CCR §§1721 and 1723.1 which would strengthen the penalty an applicant would incur for dishonest conduct during an examination as well as further clarify the penalty an applicant would incur for conveying or exposing any part of the licensing examination.

This recommendation was generated from the board's competency committee, which is responsible for the development of the CPJE examination. According to the board's current exam psychometrician, the cost to generate a new test item is $2,000/item. Compromised test items pose not only a financial loss to the board, but also inhibit the board's ability to test for minimum competency, and if an otherwise incompetent applicant passes the exam because the exam has been compromised, such a breach is a public safety issue.

Chairperson Graul advised that a copy of the language as approved by the board was provided in the meeting materials.

4. Proposed Regulation Language for Board Discussion and Possible Action

Chairperson Graul advised that these items were previously discussed during the meeting as they were included on the agenda twice.

5. Regulations Under Development

a. Proposed Amendment to 16 CCR §1780 – Update the USP Standards Reference Material

Chairperson Graul provided a brief synopsis of the proposed change to CCR §1780, which sets minimum standards for drug wholesalers. Section 1780(b) references the 1990 edition of the United States Pharmacopeia Standards (USP Standards) for temperature and humidity. The USP Standards is updated and published annually. Consequently, this section requires an amendment to §1780(b) to reflect the 2005 version of the publication and to hold wholesalers accountable to the latest standards if determined appropriate.

Chairperson Graul highlighted that because of stated concerns about whether referencing the 2005 USP standards is an unreasonable burden on wholesalers, at the October 2008 Board Meeting, the board voted to address the issue of updating the USP Standards reference materials within this section.
President Schell and Committee Chairperson Bob Graul are serving on the subcommittee and will be working with board staff and industry. Chairperson Graul requested volunteers to work with the subcommittee to address any potential concerns. Kaiser, California Society of Health-Systems Pharmacist and Western Medical Center - Santa Monica will have a representative serve on the subcommittee. Ms. Herold

indicated that she will also contact Healthcare Distribution Management Association for volunteers.

Chairperson Graul requested that board staff review the Pharmacy Law book for additional references in advance of the first subcommittee meeting.

b. Proposed Amendment to 16 CCR §1732.2 – Continuing Education for Competency Committee Members

At the October 2008 Board Meeting, the board voted to award up to six hours of continuing education (CE) credit annually to complete on-line review of examination questions if the committee member is not seeking reimbursement for their time.

Competency Committee members serve as the board's subject matter experts for the development of the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE). A committee member's term is generally about eight years.

Legislative Report

At the request of the Chairperson, Ms. Herold provided an overview of the Legislative Process.

The two year Legislative cycle began in December 2008. About one-third of the representatives are new. The board works hard to keep pharmacy law current. Beginning in December 2008, a special session was called to deal with the budget crisis. To date, this special session has not yielded any results. Legislatively all items will resolve around budget issues as they work to find a solution. Ms. Herold provided highlighted key dates on the legislative calendar including the February 27, 2009 bill submission deadline. All bills are subject to review by, at minimum, a policy committee and, if appropriate, a fiscal committee. All bills must be passed out of the house of origin by June 5, 2009. All bills must be passed by the second house by September 11 to move to the Governor. If the bill is enacted, unless otherwise specified, the bill will go into effect on January 1, 2010.

Ms. Herold also shared that bills which don't make it out of the house of origin by the deadline established can become a two year bill.

1. Legislation Sponsored by the Board of Pharmacy Omnibus Provisions from 2008

Chairperson Graul indicated that at the October 2008 Board Meeting, the board voted to pursue all omnibus provisions vetoed in SB 1779 (Senate Business and Professions Committee) which was vetoed by the Governor.

These omnibus provisions were categorized into four types of changes:

1. Use of mobile pharmacies.
2. Changes resulting in a comprehensive legal review by board staff and counsel on the legal requirements surrounding the Pharmacist-in-Charge and Designated Representative-in-Charge.
3. General omnibus provisions.
4. Omnibus provisions resulting from the recodification of Business and Professions Code section 4052.

Public Comments:

Clarification was requested on the costs to implement these provisions.

Ms. Herold responded that the cost would be negligible as the majority of the changes are noncontroversial and nonsubstantive.

Dr. Swart sought clarification about the changes to B&PC 4062 and 4110 which would allow for the use of mobile pharmacy in the event a pharmacist was undergoing a remodel. Ms. Sodgergren advised the committee that this change is not reflected as the Senate Business and Professions Committee, the author of the omnibus bill, stated that the committee will again author the omnibus bill but will not allow for any changes to the provisions contained within SB 1779.

a. Omnibus Provisions for 2009

Chairperson Graul also highlighted the omnibus provision for 2009. At the October 2008 Board Meeting, the board voted to pursue several new omnibus provisions.

Add Section 4146 – Disposal of Returned Sharps by a Pharmacy
This section needs to be added to allow a pharmacy to accept returned sharps containers from consumers for disposal.

Add Section 4013 – Subscriber Alert
This section needs to be added to require all board licensed facilities to join the board's e-mail notification list.

Amend Section 4112 – Nonresident Pharmacy: Registration; Provision of Information to Board; Maintaining Records; Patient Consultation
This section requires amendment to explicitly state that a person cannot act as a nonresident pharmacy unless he or she has obtained a license from the state.

Amend Section 4401 – Pharmacists: Biennial Renewal
This section needs amendment to require pharmacists to notify the board of any misdemeanor or felony conviction, or whether any disciplinary action has been taken, as specified, subsequent to the licensee's last renewal.

Amend Section 4403 – Reissuance Without Payment of Fees Prohibited
This section needs amendment to require pharmacy technicians and designated representatives to notify the board of any misdemeanor or felony conviction, or whether any disciplinary action has been taken, as specified, subsequent to the licensee's last renewal.

b. Immunization Proposal – Amendment to Business and Professions Code 4052 and Adoption of 4052.8

Chairperson Graul stated that at the October 2008 Board Meeting, the board voted to pursue a statutory change to allow a pharmacist to initiate and administer immunizations pursuant to the published recommendations of the Advisory Committee on Immunization Practices (ACIP).

Beginning in November 2007, board staff worked with stakeholders to address questions as well as to elicit support for this proposal for sponsorship in 2008. However, in April 2008, after consideration it was decided not to move the proposal last year due to a lack of staff as well as other legislative priorities.

Board staff is contacting potential authors for this proposal and will resume stakeholder meetings in February 2009 to solidify a broad base of support for this proposal.

Chairperson Graul indicated that a copy of the proposed language as well as a copy of the ACIP Adult and Adolescent Immunization Schedules were provided in the committee meeting materials.

Committee Comments:

Ms. Zinder questioned if the board will be able to find an author in 2009.

Ms. Herold explained why the bill was not pursued last year and highlighted that the board has support from both the California Pharmacists Association as well and the California Retailers Association. Ms. Herold underscored that this proposal is an important public health bill and ensures important training requirements.

Chairperson Graul confirmed that the key to this proposal is to solidify stakeholder support.

Dr. Swart offered to provide contact information of a pharmacist who has experience in community immunizations to assist the board.

c. Elements of a Prescription Label – Amendment to Business and Professions Code section 4076

Chairperson Graul highlighted that at the October 2008 Board Meeting, the board voted to pursue a statutory change to replace the "condition" for which a prescription is prescribed, with the "purpose" for which the medicine is prescribed. This change will clarify a pharmacist's authorization within Business and Professions Code section 4076(a)(10) and allow a pharmacist to place the "purpose" of the medication on the label that is affixed to every prescription container dispensed to a patient, if requested by the patient. This proposal is consistent with the results of the board's prescription label survey where approximately 25% of all respondents requested the purpose of the medicine be included on the label. Purpose removes the owness from the physician to provide the condition.

Committee Comments:

Dr. Swart stated that he was opposed to this proposal at the October 2008 meeting because of concerns with the implementation of such a change. At that time Dr. Swart was concerned that providing the purpose could cause a delay in providing a consumer their prescription because of the current workflow in pharmacies. Dr. Swart requested structuring the requirement to allow for a line on the prescription label where the purpose can be handwritten by the pharmacist.

Ms. Herold responded that the requirement is non-prescriptive, and the pharmacy can determine how to implement the change. She stated further that Dr. Swart's concern can possibly be addressed through the board's efforts to implement SB 472, the standardization of the prescription label. Ms. Herold indicated that staff will confirm this option with legal counsel.

Public Comments:

Steve Gray (Kaiser Permanente and the Pharmacy Foundation of California) stated support for this proposal as it allows for a dialog between the pharmacist and patient. Dr. Gray also stated that as the profession moves forward with electronic prescribing, the law will need to allow for the purpose to be collected as part of the workflow.

Based on a question from the public regarding the actual change in the proposal, Chairperson Graul stated that the purpose can be typed on the label and that if the pharmacist is unclear of the purpose of the medicine, the pharmacist may need to seek clarification from the patient or may need to contact the physician to ascertain the appropriate purpose. Chairperson Graul stated that, ideally, all physicians would provide the purpose of the prescription, however imposing that requirement is outside the scope of the board's jurisdictions.

Ms. Herold amplified why this is such an important consumer protection change.

Amy Gutierrez, representing LA County asked, procedurally, how a change would be reconciled in the event that a condition for which a medicine is prescribed is changed over time.

Ms. Herold responded that the goal is to achieve better patient outcomes.

2. Legislative Proposal Regarding Return to Medicine to Reverse Distributors

Chairperson Graul indicated that this is an action item for the committee to determine if the proposal should be an added item to the legislative calendar for 2009.

Ms. Herold provided background on the proposal, stating that over the last two years, the board has been working with sponsors of drug take back programs to ensure the appropriate disposal of unused medications. Once drugs are aggregated, they are carried back by an integrated waste hauler. Ms Herold highlighted that our law allows a pharmacy to return drugs to a wholesalers only if the drugs are going back into the drug supply, not for destruction. If drugs are to be destroyed or returned for credit, they must be returned via a reverse distributor. The proposed packet defines the criteria for a reverse distributor to perform these functions.

Chairperson Graul discussed each change by code section.

Ms. Zinder asked for clarification on the role of a reverse distributor.

Ms. Herold responded that a reverse distributor will either destroy them via incineration or send them to in antegrated waste hauler for destruction.

Dr. Swart stated that most reverse distributors are disposing of the product.

Dr. Swart suggested that the proposal allows for an estimated quantity in B&PC 4081 (b). Ms. Herold suggested that staff survey some drug manufacturers to identify how they currently determine the quantity.

Ms. Quandt (Longs/CVS) stated concern about the proposed separation of the drugs dispensed to the patient, and later returned because of a prescription error, from those that are never dispensed. Ms. Quandt advocated that in the case where a prescription was erroneously provided to a patient, it could be problematic to arrange for the destruction of the product if is it considered pharmaceutical waste. She sought clarification that a pharmacy that is not participating in the drug take back program would need to contact a reverse distributor directly in order to dispose of any drugs which were a result of a medication error.

Dr. Gray (Kaiser Permanente) suggested that the committee may want to consider a change to 4126.5 (a)(6) to specify who is included in that subsection. Dr. Gray suggested changing the language to include any entity licensed by the board and state

that such a change will help to clarify how such entities are supposed to handle the drugs

MOTION: To recommend to the board the addition of this proposal to amplify regulatory structure of reverse distributors to the board's legislative calendar for 2009.

M/S: AZ/RS

VOTE: 3 OPPOSE: 0 ABSTAIN: 0

3. Legislation Introduced Impacting the Practice of Pharmacy or the Board's Jurisdiction

Chairperson Graul provided a brief overview of two legislative proposals that were introduced impacting the practice of pharmacy.

a. AB 67 – Nava

This bill would establish the Pharmacy Patient Protection Act of 2008, which would require pharmacists to dispense all lawfully obtained prescriptions when the prescribed medication is in stock without regard to any ethical, moral, or religious objections.

b. SB 26 – Simitian

This bill would require the board to coordinate with other state agencies, local governments, drug manufacturers, and pharmacies to develop sustainable, efficient policies and programs to manage pharmaceutical wastes and the disposal of devices. The bill would authorize a pharmacy to accept the return of home-generated pharmaceutical waste and home-generated sharps waste, as defined.

Chairperson Graul indicated that copies of the bills were included in the committee meeting materials. He stated that part of the reason for the legislative overview was to highlight that it is early in the session and, thus, too early to make positions by the committee.

Ms. Zinder agreed that it is early in the session but also expressed concern about AB 67 (Nava)

Ms. Herold indicated that we are uncertain why this proposal is directed at pharmacists.

Dr. Swart stated that AB 69 is written with a broad stroke and would take away a lot of professional judgment by the pharmacist. Dr. Swart state that the board needs to watch this bill as it appears problematic.

Ms. Herold stated that board staff will seek clarification from the author's office on the proposal.

Dr. Gray requested clarification if the proposal (AB 69) nullifies some of the requirements of B&PC 733 and stated that it appears all other provisions within B&PC 733 remain in effect.

Board staff indicated that they will seek clarification from counsel.

4. Public Comment for Items Not on the Agenda

Chairperson Graul reminded the committee that it cannot discuss any of these items.

Dr. Gray requested that the board consider a modification to Health and Safety Code Section 11166 where it makes reference to 11164. Dr Gray state that Section 11164 is no longer relevant and the reference is confusing to pharmacists.

Additionally, Dr. Gray discussed B&PC 4425 which includes a statement that the Department of Health Services (DHS) (now the Department of Health Care Services) is required to provide pharmacies with a poster defining Medi-Cal pricing. Dr. Gray suggested that the board have a discussion with DHS about this requirement as DHS has never provided these posters, and pharmacies are being sued for failure to provide the information as required in B&PC 4425.

A representative from the Drug Policy Alliance (DPDP) provided an overview of the statewide program. She explained that the program is adopted on a county-by-county basis. She indicated that Los Angeles County has the most successful program thus within the state as a result of substantial support and involvement from the pharmacists within the county. Ms Garcia stated that DPDP also takes a proactive role in syringe disposal. She provided the program websites - helpstopaids.com. She thanked the board and the pharmacist community for their continued support. Ms Garcia advised the committee that the DPDP will sunset in 2010 unless they are reauthorized next year to be able continue to provide low-cost access to the pharmacists who depend on the program.

Supervising Inspector Ratcliff recommended that the committee review the requirements in California Code of Regulation section 1707.2 that define the minimum components of patient consultation. Dr. Ratcliff stated that changes to this regulation section may help underscore the importance of the consumer understanding the purpose of a prescribed medicine.

Chairperson Graul requested that all legislative and regulatory proposals be provided in writing to the board for consideration.

The meeting was adjourned at 2:11 p.m.

LEGISLATION AND REGULATION COMMITTEE

Goal 3: Advocate legislation and promulgate regulations that advance the vision and mission of the Board of Pharmacy.

Outcome: Improve the health and safety of Californians.

Objective 3.1	Annually identify and respond with legislative changes to keep pharmacy laws current and consistent with the board's mission.
Measure:	100 percent successful enactment of promoted legislative changes.
Tasks:	1. Secure extension of board's sunset date. *Sept. 30, 2006:* *Governor signs SB 1476 which delays the board's sunset date two years (until 2010), and requires the board's sunset report in 2008.* *June 2007:* *SB 963 (Ridley-Thomas) is amended to alter the sunset review process.* *July 2008:* *SB 963 (Ridley-Thomas) is amended to alter the sunset review process. Board staff attend a stakeholders meeting with committee staff to discuss amendments.* *Sept. 2008:* *Governor signs SB 963 (Chapter 385, Statutes of 2008)* 2. Sponsor legislation to update pharmacy law. *Enacted - 1st Qtr. 08/09:* *SB 1048 (Chapter 588, Statutes 2007) containing board omnibus provisions* *Oct. 2007:* *Board sponsors omnibus provisions for 2008. Four types of changes are discussed.* *(1) Omnibus changes specific to the PIC and DRC requirements* • *Section 4022.5 – Designated Representative; Designated Representative-in-Charge* • *Section 4036.5 – Pharmacist-in-Charge* • *Section 4161 – Nonresident wholesaler* • *Section 4305 – Pharmacist-in-Charge; Notice to Board; Disciplinary Action* • *Section 4329 – Nonpharmacists; Prohibited Acts* • *Section 4330 – Proprietors; Prohibited Acts* *(2) Omnibus changes to allow for the use of mobile pharmacies* • *Section 4062 Furnishing Dangerous Drugs During an Emergency.* • *Section 4110 License Required, Temporary Permit Upon Transfer of Ownership.* *(3) General omnibus changes* • *Section 4059.5 Who May order Dangerous Drugs or Devices, Exceptions.* • *Section 4081 - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory* • *Section 4126.5 – Furnishing Dangerous Drugs by Pharmacy.* • *Section 4231 – Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee.* • *H&SC 11165 – Controlled Substance Utilization Review and Evaluation System: Establishment; Operation; Funding; Reporting to Legislature.*

	(4) *Omnibus changes based on recodification of Business and Professions Code section 4052* • *Section 733 – Dispensing Prescription Drugs and Devices* • *Section 4027 – Skilled Nursing Facility – Intermediate Care Facility – Other Health Care Facilities* • *Section 4040 – Prescription; Content Requirements* • *Section 4051 – Conduct Limited to Pharmacist; Conduct Authorized by Pharmacist* • *Section 4060 – Controlled Substance – Prescription Required, Exceptions* • *Section 4076 – Prescription Container – Requirements for Labeling* • *Section 4111 – Restrictions on Prescriber Ownership* • *Section 4174 – Dispensing by Pharmacist Upon Order of Nurse Practitioner* • *H&SC 11150 – Persons Authorized to Write or Issue a Prescription* *Jan. 2008:* *Staff provides language to Senate Business and Professions Committee for inclusion in omnibus bill.* *Board approved language for omnibus bill.* *April 2008:* *Some provisions of omnibus bill removed:* • *Section 4101 – Pharmacist-in-Charge; Designation Representative-in-Charge; Termination of Status; Duty to Notify the Board.* • *Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications* • *Section 4160 – Wholesaler Licenses* • *Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked* • *Section 4362 – Entry Into Pharmacists Recovery Program.* *Oct. 2008:* *Governor vetoes SB 1779* *1st Qtr. 08/09:* *Board seeks to pursue omnibus provisions (formerly contained in SB 1779). Four areas of change discussed:* *(1) Omnibus changes specific to the PIC and DRC requirements* • *Section 4022.5 – Designated Representative; Designated Representative-in-Charge* • *Section 4036.5 – Pharmacist-in-Charge* • *Section 4305 – Pharmacist-in-Charge; Notice to Board; Disciplinary Action* • *Section 4329 – Nonpharmacists; Prohibited Acts* • *Section 4330 – Proprietors; Prohibited Acts* *(2) Omnibus changes to allow for the use of mobile pharmacies* • *Section 4062 Furnishing Dangerous Drugs During an Emergency.* • *Section 4110 License Required, Temporary Permit Upon Transfer of Ownership.*

	(3) General omnibus changes • *Section 4059.5 Who May order Dangerous Drugs or Devices, Exceptions.* • *Section 4081 - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory* • *Section 4126.5 – Furnishing Dangerous Drugs by Pharmacy.* • *Section 4231 – Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee.* *H&SC 11165 – Controlled Substance Utilization Review and Evaluation System: Establishment; Operation; Funding; Reporting to Legislature.* *(4) Omnibus changes based on recodification of Business and Professions Code section 4052* • *Section 733 – Dispensing Prescription Drugs and Devices* • *Section 4027 – Skilled Nursing Facility – Intermediate Care Facility – Other Health Care Facilities* • *Section 4040 – Prescription; Content Requirements* • *Section 4051 – Conduct Limited to Pharmacist; Conduct Authorized by Pharmacist* • *Section 4060 – Controlled Substance – Prescription Required, Exceptions* • *Section 4076 – Prescription Container – Requirements for Labeling* • *Section 4111 – Restrictions on Prescriber Ownership* • *Section 4174 – Dispensing by Pharmacist Upon Order of Nurse Practitioner* • *H&SC 11150 – Persons Authorized to Write or Issue a Prescription*
1st Qtr. 08/09:	*Board seeks to introduce 2009 omnibus changes (provisions not included in the formber SB 1779):* • *Section 4101 – Pharmacist-in-Charge; Designation Representative-in-Charge; Termination of Status; Duty to Notify the Board.* • *Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications* • *Section 4160 – Wholesaler Licenses* • *Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked* • *Section 4362 – Entry Into Pharmacists Recovery Program.* *New Provisions* • *4200.1 – Pharmacist Examination; Remedial Education* • *4112 – Non-resident Pharmacy: Registration Required* • *4146 – Return and Disposal of Sharps* • *4013 – Subscriber Alert*

3. Advocate the board's role and its positions regarding pharmacists' care and dispensing of dangerous drugs and devices (AB 2408).

Sept. 30, 2006: *Governor signs AB 2408. Amendments taken in August remove provisions that would have described the professional services provided by pharmacists, and authorized pharmacists outside California to provide pharmacists' care services to patients in California if licensed here or working within the framework of a nonresident pharmacy. Remaining provisions restructure pharmacist protocol provisions and several other changes.*

4. Secure statutory standards for pharmacies that compound medications (AB 595).

Aug. 2006: *Amendments made to remove opposition of DHS regarding pharmacy contracting with another pharmacy for compounded drugs triggers opposition from pharmacy organizations. Board drops AB 595, but will advance regulations developed for compounding pharmacies in the future.*

5. Secure implementation of e-pedigrees on prescription drugs dispensed in California.

Sept. 2006: *Governor signs SB 1476 which contains board amendments to delay implementation of the e-pedigree requirements until 2009, or upon board action, until 2011. Amendments also require interoperability, serialization, returned drug products to retain the initiating pedigree, require notice to the board of suspected or actual counterfeiting, and continuation of the pedigree through repackaging operations.*

Sept. 2008: *Governor signs SB 1307 - which delays implementation of e-pedigree.*

6. Advocate the board's position on pending legislation affecting pharmacy practice and/or the board's jurisdiction.

Oct. 2007: *Governor signs the following:*

AB 110 (Chapter 707, Statutes of 2007) Drug Paraphernalia: Clean Needle and Syringe Exchange Projects.

SB 472 (Chapter 470, Statutes of 2007) Prescription Drugs: Labeling Requirements.

SB 966 (Chapter 542, Statutes of 2007) Pharmaceutical Drug Disposal.

Governor vetoes the following:

AB 249 (Eng) Healing Arts: Settlement Agreements.

AB 543 (Plescia) Ambulatory Surgical Centers: Licensure.

AB 1025 (Bass) Professions and Vocations: Denial of Licensure.

SB 615 (Oropeza) Pharmacy Technicians: Scholarship Fund.

Oct. 2008: *Governor signs the following:*

AB 1394 (Chapter 431, Statutes of 2008) Counterfeit: Trademarks

SB 963 (Chapter 385, Statutes of 2008) Regulatory Boards: Sunset Review

Governor vetoes the following:

AB 501 (Swanson) Pharmaceutical Devices

AB 865 (Davis) State Agencies

AB1574 (Plescia) Surgical Clinics: Licensure

Jan. 2009: *Legislation introduced affecting Pharmacy law:*

(New Session) *AB 67 (Nava) Pharmacy Patient Protection Act of 2008. Dispensing of prescriptions, irrespective of a pharmacist's ethical, moral, or religious objections.*

SB 26 (Simitian) Home-generated pharmaceutical wastes and the disposal of devices.

	7. Expand the conditions under which a pharmacist may administer an immunization independent of physician protocol. *March 2007:* *Licensing Committee considers and approves concept. More work is required.* *June 2007:* *Licensing Committee considers draft language and requests additional refinements to proposal for consideration at September 2007 committee meeting.* *Sept. 2007:* *Licensing Committee forwards to full board legislative proposal.* *Oct. 2007:* *Board approved draft legislation* *Nov. 2007:* *Staff meeting with stakeholders to elicit support for the proposal.* *Dec. 2007:* *Staff develop fact sheets and work with experts in immunizations.* 8. Advocate the board's role as an advocate for consumers by redesigning prescription label for all medicines dispensed to California patients. *Oct. 2007:* *Governor signs SB 472 (Chapter 470, Statutes of 2007) Prescription Drugs: Labeling Requirements.* *Apr. 2008:* *First public forum held in Fremont.* *May 2008:* *Staff develop survey form to distribute to consumers to solicit input* *Staff attend Senior Seminar, interview attendees about prescription label and distribute surveys.* *June 2008:* *Staff attends community events, interview attendees about prescription label and distribute surveys.* *July 2008:* *Staff attends community events, interview attendees about prescription label and distribute surveys.* *Oct. 2008:* *Staff continues to attend community events, interview attendees about prescription label and distribute surveys.* *Public Education Committee updated on the status of survey results.*

Objective 3.2	Annually identify and respond with regulatory changes to keep pharmacy regulations current and consistent with the board's mission.
Measure:	Percentage successful enactment of promoted regulatory changes.
Tasks:	1. Authorize technicians to check technicians in inpatient pharmacies with clinical pharmacist programs (sections 1793.7-1793.8). *Jan. 2007:* *Office of Administrative Law approves rulemaking. Regulation takes effect.* 2. Authorize the use of prescription drop boxes and automated delivery machines for outpatient pharmacies (sections 1713 and 1717(e)). *Jan. 2007:* *Regulation takes effect following approval by the Office of Administrative Law.* 3. Make technical changes in pharmacy regulations to keep the code updated. *April 2007:* *Section 1775.4 contested citations. DCA determines no regulation is needed to accomplish the requirement to allow 1 rescheduling of an office conference. This regulation is withdrawn.* *June 2007:* *Section 1706.2 - Criteria for abandonment of files, changes take effect following approval by the Office of Administrative Law.* 4. Repeal the requirement to post a notice regarding electronic files (section 1717.2). *March 2007:* *Office of Administrative Law approves rulemaking. Regulation takes effect.* 5. Revise and update Disciplinary Guidelines revision and update (section 1760). *Aug. 2006:* *Final changes to Disciplinary Guidelines being compiled by staff.* *Dec. 2006:* *Disciplinary Guidelines is being reformatted into strikeout and underscore version for eventual release for public comment.* *June 2007:* *Enforcement Committee reviews Disciplinary Guidelines and requests additional time to review before being submitted to the board.* *Sept. 2007:* *Enforcement Committee approves Disciplinary Guidelines and recommends board approval.* *Oct. 2007:* *Board approves Disciplinary Guidelines for 45-day comment period.* *Feb. 2008:* *Regulation released for 45 days of public comment.* *April 2008:* *Board Adopts regulation.* *Sept. 2008:* *Rulemaking file submitted for review by the administration.* 6. Self-assessment of a wholesaler by the designated representative (section 1784). *April 2007:* *Office of Administrative Law approves rulemaking. Regulation takes effect.* 7. Exempt the address of records of interns from display on the board's Web site (section 1727.1). *Sept. 2006:* *Office of Administrative Law approves rulemaking. Regulation takes effect October 2006.* 8. Modification of building standards for pharmacies – rulemaking by the California Building Standards Commission. *July 2006:* *Board notified that a new procedure now exists for adopting building standards. Staff will pursue these procedures in 2007.* *June 2007:* *Board staff submit rulemaking file to the California Building Standards Commission.*

9. Update Notice to Consumers Poster in conformance with AB 2583 (Chapter 487, Statutes 2006)(Section 1707.2).

Feb. 2007: *Board notices regulation for 45 days comment period.*

April 2007: *Board considers comments submitted during public comment period and modifies text regulation to reflect comments.*

May 2007: *New section 1707.2 released for 45 days of public comment.*

July 2007: *Board adopts regulation and compiles rulemaking file. File submitted to the Department of Consumer Affairs to initiate Administration Review.*

Sept. 2007: *File submitted to the Office of Administrative Law for review.*

Oct. 2007: *Office of Administrative Law approves rulemaking.*

Nov. 2007: *Regulation changes takes effect.*

Nov. 2007: *Staff solicits design submissions from graphic designers.*

Jan. 2008: *Communication and Public Education Committee make recommendations on design submissions.*

Jul. 2008: *Board mails updated Notice to Consumers to all pharmacies in California.*

10. Secure changes without regulatory effect (Section 100 changes) to pharmacy regulations to keep them accurate and current.

Dec. 2007: *Office of Administrative Law approves Section 100 Changes.*

Amend the following:

1707 – Waiver of requirements for off-site storage of records

1709.1 – Designation of pharmacist-in-charge

1715 – Self-assessment of a pharmacy by the pharmacist-in-charge

1717 – Pharmacy practice

1746 – Emergency contraception

1780.1 – Minimum standards for veterinary food-animal drug retailers

1781 – Exemption certificate

1787 – Authorization to distribute dialysis drugs and devices

1790 – Assembling and packaging

1793.8 – Technician check technician

Repeal section 1786 – Exemptions

11. Increase fees to keep the board's contingency fund solvent and maintain operations.

Nov. 2007: *Office of Administrative Law approves rulemaking.*

Nov. 2007: *Staff complete necessary programming changes and begin advising licensees of the change.*

Jan. 1, 2008: *New fees take effect.*

12. Secure regulatory standards for pharmacies that compound.

Dec. 2006: *Licensing Committee evaluates proposed compounding regulations developed in 2004. Some modifications may be needed.*

March 2007: *Licensing Committee convenes discussion of amendments to compounding regulations. More work is required.*

May 2007: *Licensing Committee holds detailed discussion on compounding regulations.*

Sept. 2007: *Licensing Committee forwards regulation proposal to the board for review.*

Nov. 2007: *Board releases language for the 45-day comment period.*

Jan. 2008: *Board held regulation hearing and considers written comments and oral testimony.*

April 2008: *Board votes to withdraw rulemaking.*

Aug. 2008: *Board releases new language for the 45-day comment period.*

	13. Establish an ethics course. *April 2007:* *Board establishes a subcommittee to examine the development of an ethics course.* *Oct. 2007:* *Board votes to pursue regulation change to establish program components.* *Sept. 2008:* *Board notices regulation for 45-day comment period.* *Oct. 2008:* *Board votes to pursue 15-day comment period and, absent any negative comments, authorizes the Executive Officer to complete the rulemaking file.*

Objective 3.3	Review five areas of pharmacy law for relevancy, currency and value for consumer protection by June 30, 2011.
Measure:	Number of areas of pharmacy law reviewed.
Tasks:	1. Initiate review of the pharmacist-in-charge requirement. *Aug. 2007:* *Staff and counsel review pharmacist-in-charge and designated representative-in-charge statutes and regulations for reporting requirements and make recommendations to amend various statutes and regulations.* *Oct. 2007:* *Legislation and Regulation Committee reviews draft language to be incorporated into omnibus bill.* *Jan. 2008:* *Board approves omnibus language recommended by Legislation and Regulation Committee.* • *Section 4022.5 – Designated Representative; Designated Representative-in-Charge* • *Section 4036.5 – Pharmacist-in-Charge* • *Section 4101 – Pharmacist-in-Charge; Designation Representative-in-Charge; Termination of Status; Duty to Notify the Board.* • *Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications* • *Section 4160 – Wholesaler Licenses* • *Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked* • *Section 4305 – Pharmacist-in-Charge; Notice to Board; Disciplinary Action* • *Section 4329 – Nonpharmacists; Prohibited Acts* • *Section 4330 – Proprietors; Prohibited Acts* *April 2008:* *The following provisions are not incorporated into omnibus bill.* • *Section 4101 – Pharmacist-in-Charge; Designation Representative-in-Charge; Termination of Status; Duty to Notify the Board.* • *Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications* • *Section 4160 – Wholesaler Licenses* • *Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked* *Sept. 2008:* *Governor vetoes SB 1779.* *Jan. 2009:* *Board seeks to reintroduce provisions contained in SB 1779 via omnibus bill.*